EXHIBIT DX1

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

Forced-air warming: a source of airborne contamination in the operating room?

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Abstract

Forced-air-warming (FAW) is an effective and widely used means for maintaining surgical normothermia, but FAW also has the potential to generate and mobilize airborne contamination in the operating room.

We measured the emission of viable and non-viable forms of airborne contamination from an arbitrary selection of FAW blowers (n=25) in the operating room. A laser particle counter measured particulate concentrations of the air near the intake filter and in the distal hose airstream. Filtration efficiency was calculated as the reduction in particulate concentration in the distal hose airstream relative to that of the intake. Microbial colonization of the FAW blower's internal hose surfaces was assessed by culturing the microorganisms recovered through swabbing (n=17) and rinsing (n=9) techniques.

Particle counting revealed that 24% of FAW blowers were emitting significant levels of internally generated airborne contamination in the 0.5 to 5.0 μm size range, evidenced by a steep decrease in FAW blower filtration efficiency for particles 0.5 to 5.0 μm in size. The particle size-range-specific reduction in efficiency could not be explained by the filtration properties of the intake filter. Instead, the reduction was found to be caused by size-range-specific particle generation within the FAW blowers. Microorganisms were detected on the internal air path surfaces of 94% of FAW blowers.

The design of FAW blowers was found to be questionable for preventing the build-up of internal contamination and the emission of airborne contamination into the operating room. Although we did not evaluate the link between FAW and surgical site infection rates, a significant percentage of FAW blowers with positive microbial cultures were emitting internally generated airborne contamination within the size range of free floating bacteria and fungi (<4 μm) that could, conceivably, settle onto the surgical site.

Introduction

Forced-air warming (FAW) has been widely adopted in clinical practice to prevent inadvertent surgical hypothermia. This is based upon the well established benefits of surgical normothermia which include reduced operative blood loss,[1] improved wound healing,[2] reduced duration of hospital stay,[3] increased survival,[4] and reduced wound infection.[3] Although FAW is one of several methods available for maintaining surgical normothermia, it has the potential to mobilize and generate airborne contamination in the operating room from FAW airflow which other methods of warming do not.

Airflow-free alternatives to FAW, such as resistive-heating technologies, have been shown to be comparably effective to or better than FAW for maintaining surgical normothermia.[5-15] Given these clinically validated warming alternatives, research is needed to assess the relationship between FAW and airborne contamination, as a surrogate risk of infection, in the operating room. This is particularly relevant as there has not been a study of surgical site infection (SSI) rates after FAW compared with a normothermic control population, nor is there likely to be, bearing in mind the numbers of patients that might be needed to show a statistically significant difference if one exists.

Airborne contamination consists of all particulate matter suspended in the operating room air. Common forms include microbial-laden dust, lint, skin squames, and respiratory droplets.[16-18] These contaminants are mobilized by air currents and have been shown to settle out of the air onto the surgical site, contributing to the risk of a surgical site infection (SSI) through at least two possible mechanisms: pathogenic contaminants can be the direct cause of SSI; non-pathogenic contaminants can enable SSI through the forming of a nidus for pathogen growth and attachment.[19] Most FAW devices contain a "0.2 μm rated" intake filter[20] to prevent the devices from becoming internally contaminated and to lessen the mobilization of airborne contamination in the operating room. However, several studies have reported colonization[21-23] on the internal surfaces of the warm-air blower devices and one study was able to repeatedly culture microbes from the blower's airstream;[21] this study recommended the placement of a distal hose end filter to lessen FAW microbial emissions.

In contrast, other studies assessing settle plate colonization levels did not detect significant differences following the use of FAW[24-26] in the operating room; the conclusion made was that FAW posed no incremental airborne contamination risk. To the authors' knowledge, studies have not examined the relationship between FAW and the spread of non-viable forms of airborne contamination.

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Key words: forced-air warming.

Funding: study funding provided by Augustine Biomedical + Design Eden, Prairie, Minnesota, USA.

Received for publication: 11 September 2009.
Accepted for publication: 17 October 2009.

Orthopedic Reviews 2009; 1:e28
doi:10.4081/or.2009.e28

Therefore, in this study we investigated the emission of both viable and non-viable forms of airborne contamination from FAW blowers in several hospitals, with assessment of microbial colonization on the internal hose surfaces.

Materials and Methods

Sampling procedures

FAW blowers, from hospitals in the vicinity of Minneapolis and St. Paul, MN, USA, were sampled after-hours in the operating room to quantify the levels of contamination caused by airborne emissions and bacterial colonization on internal hose surfaces.

Contamination caused by airborne emissions from the FAW blowers was recorded using a Handilaz™ laser particle counter (Particle Measuring Systems, Boulder, CO, USA) with a 0.1 ft^3 sample volume. Particle counts were taken at the intake and distal hose end airstreams: for the intake sample, the probe was placed at 1-2 inches from the intake filter; for the distal sample, the probe was placed 1-2 inches inside the distal hose end. Two or more samples were taken at each location.

Bacterial colonization of the internal hose surfaces was sampled through the following swabbing and rinsing techniques: pre-moistened swabs were rubbed against portions of the internal air-path surfaces of the injection molded proximal (unit-end) and distal (output-end) hose fittings; 100 mL of sterile water was poured into the unit hose and mechanically agitated by gently rolling and elevating the hose until the internal surfaces had been rinsed twice.

Assessments

Microbiological culturing and analysis was

performed by PACE Analytical, Oakdale, MN, USA.

The filtration efficiency of FAW blowers was calculated as the mean within-device reduction in particle counts for the distal as compared to intake airstream. Filtration efficiencies were segmented for the particle size ranges of 0.3 to 0.5 μm, 0.5 to 5.0 μm, and greater than 5.0 μm. FAW blowers which displayed an abnormal filtration efficiency pattern, where the efficiency at 0.3 to 0.5 μm exceeded the efficiency at 0.5 to 5.0 μm, were classified as "abnormally operating"; FAW blowers which displayed a normal filtration efficiency pattern, where the efficiency at 0.5 to 5.0 μm exceeded the efficiency at 0.3 to 0.5 μm, were classified as "normally operating". Scatter plots of average FAW blower intake compared with distal air-stream particle counts, grouped by FAW blower classification, were used to calculate expected filtration efficiencies and identify outlying units (see *Statistical analysis*). Bar charts of statistically significant abnormally operating units were created by plotting intake, distal, and expected distal particle counts by unit, with expected distal particle counts calculated as the product of expected filtration efficiency and observed intake particle count.

Colony forming units (CFU) per swab were assessed by the following process: swabs were transported from the site in 10 mL of Butterfield's buffer on ice; the diluent and swab were vortexed in transport container for 30 seconds; the diluent was filtered through a 0.45 μm nitrocellulose membrane filter; the filter was plated on tryptic soy agar, a non-selective medium; incubation was performed for 48 hours at 36.5±2ºC; and plates were inspected for growth and micro-organisms counted as CFU per swab.

CFU per rinse were assessed by the following process: the rinse solution was transported from the site in sterile whirl pack bags on ice; the rinse solution was filtered through a 0.45 μm nitrocellulose membrane filter; the filter was plated on tryptic soy agar, a non-selective medium; incubation was performed for 48 hours at 36.5±2ºC; and plates were inspected for growth micro-organisms counted as CFU per 100 mL rinse.

Statistical analysis

For the normally operating population, a simple no-intercept ANCOVA model was fitted to within-unit means of the following: a response variable for distal hose end particles 0.5 to 5.0 μm/ft^3; and a predictor variable for intake particles 0.5 to 5.0 μm/ft^3. Expected FAW blower filtration efficiency for 0.5 to 5.0 μm particle size range is defined as the predicted percent reduction in distal hose end particles/ft^3, relative to intake particles/ft^3, based upon the ANCOVA least squares parameter estimates. For each FAW blower in the abnormally operating population, tests of hypothesis were conducted to determine the probability that the observed distal hose end particle deviation from expected was due to random variation using the following procedure: the 0.5 to 5.0 μm particles/ft^3 deviation from expected was calculated using the normally operating population ANCOVA model parameter estimates; a t-value was calculated by dividing this deviation by the square root of the ANCOVA model's mean square error; and a one-tailed probability was assessed from a t-distribution with degrees of freedom equal to that of the ANCOVA model. Reported P-values were not adjusted for family confidence intervals.

Results

FAW blowers were sampled in the operating rooms from 5 locations, representing a full spectrum of hospital sizes (Table 1); particle counts were performed on 25 blowers, swabs were collected from 17 blowers, and hoses were rinsed on 9 blowers. The three forms of sampling were not undertaken on mutually exclusive blowers.

Airborne contamination (particle counting)

A line plot of FAW blower filtration efficiency by particle size range revealed that 8 of 25 blowers were operating abnormally, meaning they had lower filtration efficiencies in the particle size range of 0.5 to 5.0 μm than in the size range of 0.3 to 0.5 μm (Figure 1). The magnitude of airborne contamination generated by abnormally operating units is displayed as a plot of average distal versus intake particle counts per cubic foot by unit in the size range of 0.5 to 5.0 μm (Figure 2). As indicated, particle emissions from normally operating blowers are clustered around the trend line of expected filtration efficiency (94.1%); particle emissions from abnormally operating blowers are generally greater than expected, with 6 of 8 blowers showing significant deviations from the trend line. The magnitude of this deviation is further highlighted in a bar chart of intake, distal, and expected distal particle counts per cubic foot for abnormally operating blowers in the size range of 0.5 to 5.0 μm (Figure 3). As shown, distal particle emissions are greater than expected for blowers 3 through 8, resulting in lowered filtration efficiencies ranging from 17% to 81% for these blowers.

Table 1. Hospital demographics and number of FAW blowers sampled via particle counting, swabbing, and rinsing.

Hospitals sampled (number of operating rooms)	
Hospital A	1 to 5
Hospital B	6 to 12
Hospital C	13 or more
Hospital D	1 to 5
Hospital E	1 to 5
Forced-air warming blowers sampled, (n)	
Particle counting	25
Swabbing	17
Rinsing	9

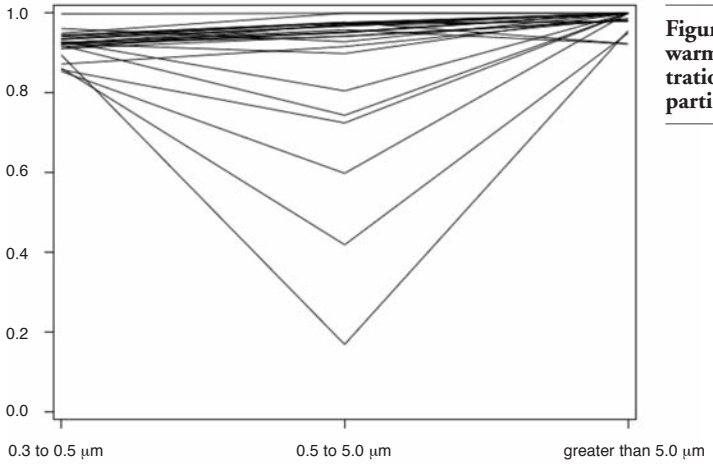

Figure 1. Forced-air warming blower filtration efficiency by particle size range.

Bacterial contamination (swabbing and rinsing)

Swabs taken from the internal hose surface detected bacterial colonization rates of 71% and 88% for the proximal and distal locations respectively (Table 2), with 2 of 17 distal samples showing colonization levels above the limits of detection used in the study, and only one of 17 units showing no colonization at either location. Rinsing detected bacterial colonization of 89% on the internal hose surfaces of the 9 units sampled.

Discussion

This study quantified levels of airborne particle emission from FAW blowers which were in use in a hospital operating room environment. Thirty-two percent of the blowers investigated appeared to exhibit abnormal filtration efficiency patterns that were suggestive of airborne contaminant generation inside the blowers. The filtration efficiency trends shown in Figure 1 illustrate the differences between "normally" and "abnormally" operating blowers. Normal depth-filters exhibit increasing filtration efficiency as particle sizes increase from 0.3 μm,[27] and this trend is clearly shown in the blowers classified as "normal". This is understandable because depth-filters are most easily penetrated by 0.3 μm sized particles and less easily penetrated by larger particles. Blowers classified as "abnormal" showed decreasing filtration efficiency in the 0.5 to 5.0 μm particle range. In other words, more particles were emitted from the blowers in the 0.5 to 5.0 μm size range than expected. If air leaks in or around the filter were responsible for the 0.5 to 5.0 μm reduction in efficiency, one would expect to see a proportional reduction in filtration efficiency for each particle size range. It appears, therefore, that 32% of the blowers tested were emitting internally generated airborne contamination with a mean particle size of 0.5 to 5.0 μm. Furthermore, 6 of the 8 abnormal blowers were emitting significant levels of airborne contamination (Figures 2 and 3).

The presence of microbes on air path surfaces in 94% of the blowers suggests that a viable component could be present in the emitted contaminants (Table 2). Common operating room airborne microbes in the 0.5 to 5.0 μm size range include unclumped bacteria (<4 μm) and fungi (<4 μm).[28] Non-viable sources may have included particles generated from moving components, which can become buoyant airborne carriers of microbes. Additionally, CFUs detected by rinsing were lower than CFUs detected by swabbing, even though the rinsing technique sampled a larger

Table 2. CFU detected per site for swabbing and rinsing sampling techniques.

	Swabbing		Rinse
	Proximal hose end (CFU/Site)	Distal hose end (CFU/Site)	Internal hose surface (CFU/100mL)
Hospital A			
Bair hugger 505, unit 1	3	6	8
Bair hugger 505, unit 2	2	3	6
Bair hugger 505, unit 3	2	1	7
Bair hugger 505, unit 4	0	0	
Bair hugger 505, unit 5	0	2	
Hospital B			
Bair hugger 505, unit 6	2	11	4
Bair hugger 505, unit 7	6	102	6
Bair hugger 505, unit 8	0	9	5
Hospital C			
Bair hugger 505, unit 9	1	>300*	0
Bair hugger 505, unit 10	1	>300*	1
Bair hugger 505, unit 11	24	0	1
Hospital D			
Bair hugger 505, unit 12	1	3	
Bair hugger 505, unit 13	0	7	
Bair hugger 505, unit 14	1	2	
Bair hugger 505, unit 15	1	7	
Bair hugger 505, unit 16	0	32	
Bair hugger 505, unit 17	2	7	
Percentage of samples colonized, (%)	71	88	89

*Bacterial colonies were too numerous to count on plates.

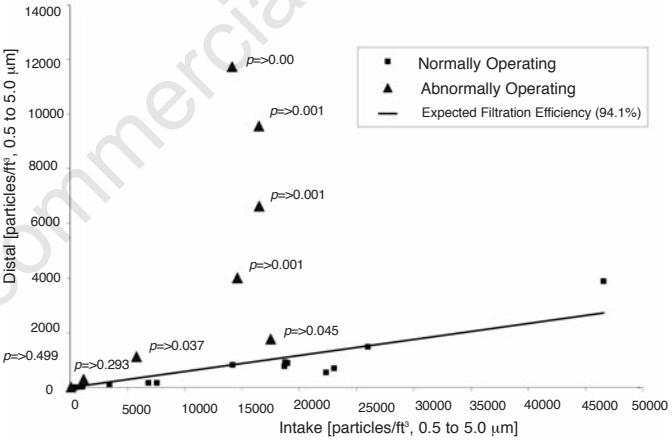

Figure 2. Average distal versus intake particles/ft³ in the 0.5 to 5.0 μm size range by FAW blower

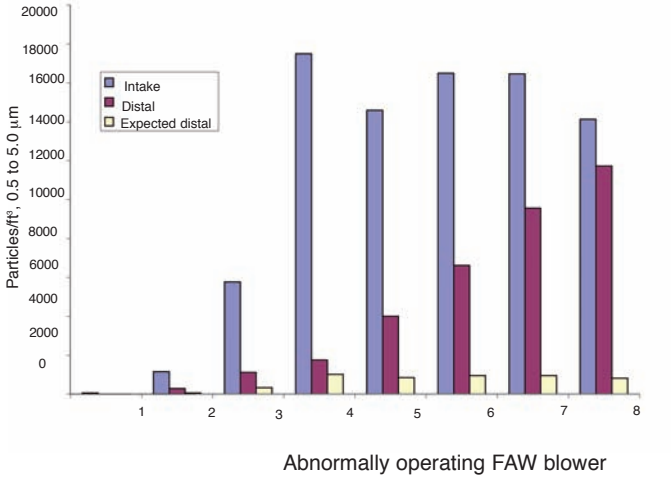

Figure 3. Average intake and distal particles/ft³ plotted alongside expected distal particles/ft³ for the abnormally operating blower population by blower.

surface area than the swabbing technique. The most likely explanation for this is that the bacteria were encapsulated in a biofilm barrier that required mechanical debridement to dislodge them during sampling.[19] The implication is that the measured bacterial colonization at each site could be artificially low.

The clinical significance of these findings relates to the link between airborne contamination and SSI, which has been well established.[29] It has been estimated that 98% of the bacterial contamination found in a surgical site is deposited from the air.[30,31] Research has also shown that implantation of foreign materials, such as vascular or orthopedic prostheses, greatly reduces the inoculum of bacterium needed to initiate an infection; for some materials the inoculum required to cause a SSI is reduced 10,000-fold.[31] Therefore, SSI may result from the implant being contaminated by a few organisms,[32] or in some orthopedic cases even a single *Staphylococcus aureus* bacterium may be sufficient.[33] Although the present study did not evaluate the link between FAW and SSI rates, the findings in this study and those of others[21-23] suggest that bacteria colonize the internal air path surfaces of the majority of FAW blowers. The findings also suggest that a significant percentage of FAW blowers are emitting particulates, which were shown to originate inside the blowers. Given that the air effluent from FAW blowers passes through a warming blanket that vents the effluent in close proximity to the surgical site, particulate emission from FAW blowers could, conceivably, be deposited onto the surgical site, which would be of particular importance for the most contamination-sensitive procedures.

This study has also shown that the design of forced-air warming equipment is questionable for preventing the emission of airborne contamination. European Union Medical Device Directives require that reusable medical equipment should allow decontamination;[34] US Food and Drug Administration and Health Canada make a similar statement,[35,36] but the statement is currently a recommendation, and not a requirement. Operating instructions from FAW manufacturers do not provide a method for decontaminating the inside of the hose or the blower. Additionally, particle counting showed that the intake filter was not HEPA rated. The observed efficiency of the intake filter was 93.5% for particles over 0.3 μm in the current study, which is below the rating of a "true HEPA" filter, which by definition eliminates more than 99.97% of particles over 0.3 μm in size. With 93.5% efficient intake filtration, 6.5% of particulates over 0.3 μm are passing through the intake filter into the blower. The passage of these particulates may lead to contamination of the blower's interior surfaces or emission of the particulates into the warming blanket. As such, other authors have suggested the implementation of a distal hose end-filter.[21]

Based upon the results of this study, FAW manufacturs should consider re-designing FAW blowers to ensure compliance with mandates for internal decontamination and provide certifiable "true HEPA" filtration. Clinicians should be aware that FAW blowers emit more than just hot air and that alternative technologies to prevent inadvertent perioperative hypothermia exist.

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EXHIBIT DX2

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room

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Background: Forced-air warming (FAW) is widely used to prevent hypothermia during surgical procedures. The airflow from these blowers is often vented near the operative site and should be free of contaminants to minimize the risk of surgical site infection. Popular FAW blowers contain a 0.2-μm rated intake filter to reduce these risks. However, there is little evidence that the efficiency of the intake filter is adequate to prevent airborne contamination emissions or protect the internal air path from microbial contamination buildup.

Methods: Five new intake filters were obtained directly from the manufacturer (Bair Hugger 505, model 200708D; Arizant Healthcare, Eden Prairie, MN), and 5 model 200708C filters currently in hospital use were removed from FAW devices. The retention efficiency of these filters was assessed using a monodisperse sodium chloride aerosol. In the same hospitals, internal air path surface swabs and hose outlet particle counts were performed on 52 forced-air warming devices (all with the model 200708C filter) to assess internal microbial buildup and airborne contamination emissions.

Results: Intake filter retention efficiency at 0.2 μm was 93.8% for the 200708C filter and 61.3% at for the 200708D filter. The 200708D filter obtained directly from the manufacturer has a thinner filtration media than the 200708C filter in current hospital use, suggesting that the observed differences in retention efficiency were due to design changes. Fifty-eight percent of the FAW blowers evaluated were internally generating and emitting airborne contaminants, with microorganisms detected on the internal air path surfaces of 92.3% of these blowers. Isolates of *Staphylococcus aureus*, coagulase-negative *Staphylococcus*, and methicillin-resistant *S aureus* were detected in 13.5%, 3.9%, and 1.9% of FAW blowers, respectively.

Conclusion: The design of popular FAW devices using the 200708C filter was found to be inadequate for preventing the internal buildup and emission of microbial contaminants into the operating room. Substandard intake filtration allowed airborne contaminants (both viable and nonviable) to penetrate the intake filter and reversibly attach to the internal surfaces within the FAW blowers. The reintroduction of these contaminants into the FAW blower air stream was detected and could contribute to the risk of cross-infection. Given the deficiencies identified with the 200708C intake filter, the introduction of a new filter (model 200708D) with substantially lower retention efficiency is of concern.

Key Words: Surgical site infection; patient warming; laminar air flow; operating room environmental contamination; filtration.

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Conflict of interest: David Leaper chaired the NICE guideline on SSI prevention and treatment, is a member of the Antimicrobial Resistance and Healthcare Associated Infection advisory committee in the UK, and has served as a consultant/paid lecturer to several healthcare companies in relation to SSI. Mark Albrecht is a researcher funded by Augustine Biomedical + Design. None of the other authors have any conflicts of interest to report.

0196-6553/$36.00

doi:10.1016/j.ajic.2010.06.011

Forced-air warming (FAW) has been widely adopted in clinical practice to prevent inadvertent hypothermia. This is based on the well-established benefits of normothermia during operative procedures, including reduced operative blood loss, improved wound healing, reduced duration of hospital stay, improved survival, and reduced rates of surgical site infection (SSI).[1-6] The airflow from these FAW devices is often vented into the sterile field adjacent to the operative site and ideally should be free of contaminants to minimize the risk of SSI. Popular FAW devices currently in widespread use contain a 0.2-μm rated intake filter to reduce this risk.[7] However, we are not aware of any published evidence demonstrating sufficient efficiency of the intake filter to prevent airborne contamination emissions or to protect the internal air path from a buildup of microbial contamination.

Airborne contamination comprises all particulate matter suspended in the operating room (OR) air. Common forms include microbial-laden dust, fibers from theatre clothing and operative drapes, desquamated skin, and respiratory droplets.[8-10] These contaminants are mobilized by air currents and have been shown to settle out of the air onto the operative site, contributing to the risk of a SSI through at least two likely mechanisms. Pathogenic contaminants can directly cause an SSI, and nonpathogenic contaminants can lead to an SSI through the formation of a nidus for microbial attachment and growth.[11] A high level of airborne contamination at the operative site is not necessary; the risk of a superficial or deep SSI increases exponentially in the presence of a foreign body, such as a hip or knee prosthesis.[12,13]

To limit the associated risks of airborne contamination, OR ventilation is designed to meet a minimum filtration efficiency standard of 90%.[14] For many contamination-sensitive operations, particularly in the orthopedic and cardiovascular fields, ORs routinely use high-efficiency particulate air (HEPA) ventilation for added protection. By definition, HEPA filtration meets minimum filtration efficiency standards of 99.97% at 0.3 μm. As mentioned previously, most FAW devices use a 0.2-μm rated intake filter to prevent the emission of airborne contamination. A filter's micron rating conveys no information about its quality, however. The key parameter is the "filtration efficiency," or "retention efficiency," at the stated micron rating. The manufacturers of FAW blowers do not disclose the filtration efficiency of their intake filters,[7] making it difficult to evaluate the adequacy of FAW intake filters for preventing the mobilization of airborne contaminants in the OR. Furthermore, we recently identified a number of FAW devices that were emitting excessive levels of airborne contamination in an OR environment, apparently related to airborne contaminants penetrating the intake filter over a prolonged period.[15]

In terms of preventing a buildup of internal microbial contamination, the FAW blower intake filter has been deemed deficient by a number of researchers. Previous studies have routinely found microbial colonization inside the majority of sampled FAW blowers.[16-18] One study repeatedly cultured microbes from the blower's airstream; the authors recommended placement of a distal hose end filter to reduce the risk of microbial emissions.[16] Some other studies assessing settle plate colonization levels have not detected any significant differences with the use of FAW in the OR, however.[19-21] The results of those studies are difficult to interpret, given that only a small number of FAW blowers were sampled and the fact that the investigators did not take into account the possibility that these FAW blowers might or might not have been internally contaminated based on their hours of use and number of environmental exposures.

Because of the perceived infection risks, many ORs have been reluctant to use FAW to maintain normothermia.[22] Air-free alternatives to FAW have been developed, including conductive mattresses and blankets that have been shown to be comparably effective in randomized clinical trials[23-29] and do not pose a similar risk of airborne contamination. With the availability of these clinically validated alternatives, it is important to assess whether the design of FAW blowers is adequate for preventing airborne contamination emissions in the OR. Given the critical role of the intake filter in preventing contamination emissions and buildup within FAW blowers, the present study focused on (1) rating the retention efficiency of two popular types of pleated gas intake FAW filters, using industry filtration challenge standards; (2) assessing the performance of FAW filters in the environment of use (the OR), by isolating the filters from the FAW devices and challenging them on a special test fixture; (3) quantifying airborne contaminants in the effluent air stream that were generated downstream of the intake filter within the FAW blower; and (4) culturing the internal FAW blower internal air path surfaces for buildup of microbial contamination.

METHODS

Sampling Procedures

FAW blowers in the ORs of hospitals in the vicinity of Minneapolis and St Paul were sampled after hours to quantify the following:

1. Emission of airborne contamination from the distal air stream, recorded using a calibrated laser particle counter (Handilaz Mini; Particle Measuring Systems, Boulder, CO). Particle counts were taken within the intake and distal hose end airstreams. For the intake sample, the probe was placed 2-5 cm from the intake filter; for the distal sample, the probe was placed 2-5 cm inside the distal hose end. Three 1-minute 0.1-ft^3 samples were taken at each location.
2. Performance of the intake filter in the OR environment, measured separately from the FAW blower using a portable test fixture that challenged the intake filter with ambient operating room air. The fixture consisted of a downstream vacuum (calibrated to draw 35 ft^3/min of ambient operating room air through the filter), a mounting plate, and an internal particle sampling pitot tube located downstream of the filter in the center of the air channel before the vacuum. With the intake filter affixed to the fixture and the vacuum running, particle counts of a 0.1-ft^3 sample volume were taken upstream and

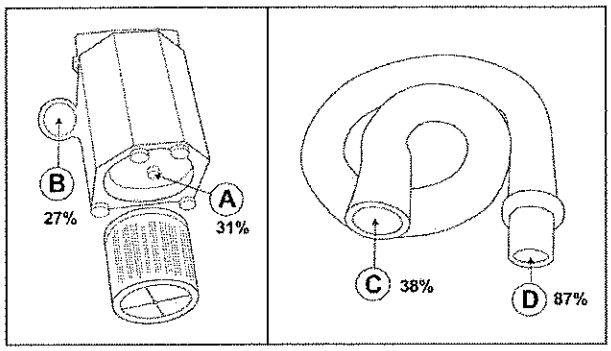

Fig 1. Detection rates for nonspecific microorganisms on FAW blower (n = 52) internal air path surfaces by swabbing location: (A) motor stack, (B) elbow, (C) proximal hose end, and (D) distal hose end.

downstream of the intake filter. For the upstream sample, the probe was placed 2-5 cm from the exposed filter media surface; for the downstream sample, the probe was coupled to the sampling pitot tube using a 7-cm tubing extension. Three samples were taken at each location.

3. Microbial colonization of the internal air path surfaces, sampled using swabs moistened with Butterfield's buffer solution. Moistened swabs were rubbed against an ~10-cm^2 area of the following internal air path surfaces (Fig 1): exposed plastic surfaces of structure supporting the motor directly downstream of the intake filter, injection molded elbow connecting the proximal hose to the unit, and injection molded proximal (unit end) and distal (output end) hose fittings. Four control swabs, representing the swab set for a complete unit, were also obtained simultaneously and sent to the microbiology laboratory in a blinded fashion with the active samples. The control swabs were obtained by moistening the swab with Butterfield's buffer and placing the swab directly into its transport container.

Intake FAW blower filters were acquired for further testing both in new condition directly from the manufacturer (Arizant Healthcare, Eden Prairie, MN) and in used condition from FAW devices in use in ORs for quantification of intake filter retention efficiency, measured by challenging the filters through a range of monodisperse particle sizes (0.025-0.5 μm). An industry standard filtration test fixture used a blower and HEPA filtration to remove all ambient particulate from the challenge air. An atomizer (Quant Technologies, Blaine, MN) provided a polydisperse NaCl aerosol to an aerosol neutralizer (model 3077; TSI, Shoreview, MN), which used a krypton-85 radiation source to neutralize the particle charge distribution to Boltzmann equilibrium levels. An electronic classifier (model 3080; TSI) then selected a portion of the polydisperse NaCl aerosol based on its electronic mobility diameter, thereby producing a monodisperse NaCl aerosol. This monodisperse NaCl aerosol was injected into the challenge airstream. Upstream and downstream particle concentrations were measured simultaneously using two condensation particle counters (models 3772 and 3782; TSI). An air velocity meter (Dwyer Instruments, Michigan City, IN) was used to record the challenge airflow (range, 30-45 ft^3/min).

Assessments

Microbiological culturing and analysis were performed by PACE Analytical (Oakdale, MN). Assessments of intake filter retention efficiency were performed by CT Associates Inc (Eden Prairie, MN). Filter retention efficiency was calculated as the fraction of particles captured by the filter over a 5- to 10-minute challenge period in the industry standard filtration challenge test fixture. Retention efficiencies were measured for each filter at 6 monodisperse particle challenge sizes: 0.025 μm, 0.05 μm, 0.1 μm, 0.2 μm, 0.3 μm, and 0.4 μm; some filters were challenged at a seventh particle size of 0.5 μm. Challenge concentrations varied from 85,000 to 1,100,000 particles/ft^3, depending on particle size. The most penetrating particle size (MPPS) was defined as the particle size at which the filter displayed a minimum retention efficiency.

Intake filter performance in the OR environment was assessed as the fraction of particles >0.3 μm captured by the intake filter when challenged by ambient operating room air on the portable test fixture. A 6-minute challenge period was used for each filter, during which upstream and downstream measurements were performed sequentially. Reported values for upstream particles were calculated as the average particle concentration upstream of the intake filter. Similarly, reported values for downstream particles were calculated as the average particle concentration downstream of the filter.

Expected distal airstream particle emissions were calculated for each FAW blower by (1) computing the average concentration of >0.3-μm particles in the intake airstream and (2) multiplying the average intake airstream particle concentration by the fraction of >0.3-μm particles removed by the intake filter (as observed during intake filter performance testing). Intake airstream particle concentrations were measured over a 3-minute sampling period.

Deviations from expected distal airstream particle emissions were calculated for each FAW blower by subtracting the expected distal airstream particle concentration from the observed distal airstream concen-tration of >0.3-μm particles. Distal airstream particle concentrations were measured over a 3-minute

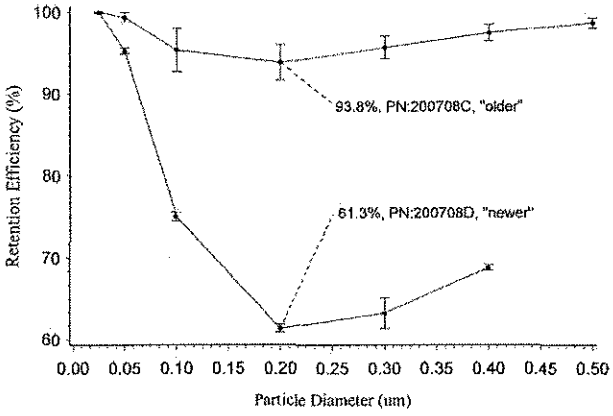

Fig 2. Mean retention efficiencies for intake filter models 200708C (n = 5) and 200708D (n = 5) with dispersion indices (± 1 standard deviation). For each filter, the efficiency rating at the most penetrating particle size is shown.

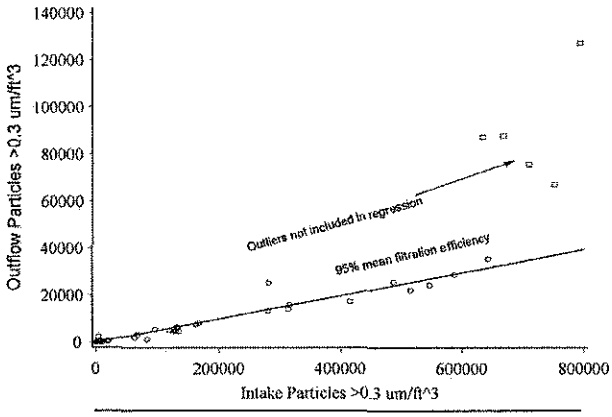

Fig 3. Intake filter performance in the surgical environment of use as assessed with the OR room challenge fixture (not shown). Individual intake filter performance values (n = 52) are displayed, along with a fitted no-intercept linear regression model.

sampling period. The deviation from expected distal airstream particle emission represents the quantity of particulate emission generated inside the FAW blower downstream of the intake filter.

The number of colony-forming units (CFUs) per swab was assessed as follows. Swabs were transported from the site in 5 mL of Butterfields's buffer on ice. The diluent and swab were vortexed in a transport container for 30 seconds. In duplicate, 1 mL of the sample was pipetted into a Petri dish, and 25 mL of molten 45°C tryptic soy agar was added to form a nonselective growth medium. After incubating for 48-72 hours at 36.0 ± 0.1°C, the dishes were inspected for microorganism growth, with each individual colony counted as a single CFU. The reported number of CFUs per swab represents the average colony counts recorded between the two Petri dishes multiplied by a conversion factor of 5. The reported counts for the distal hose, proximal hose, elbow, and motor stack are the CFUs reported for the single swab used at each location (Fig 1). Combined CFUs per FAW blower are the sum of the CFUs reported at each of the 4 swabbing locations.

The presence of specific microorganisms was assessed for each swab through enriching and incubating the remaining diluent (24 hours at 36.0 ± 0.1°C), followed by testing for *Staphylococcus aureus* and coagulase-negative *Staphylococcus* (CoNS) using mannitol salt agar and for methicillin-resistant *S aureus* (MRSA) using CHROMagar (BD, Franklin Lakes, NJ). No other *Staphylococcus* species were identified.

Statistical analysis

FAW blowers with significant deviations from expected distal air stream particle emissions were identified using a variance-weighted analysis of covariance model with particle outflow concentration as the response. Predictors included intake particle concentration as a covariate and FAW blower serial number and treatment (filter isolated or filter on FAW blower) as fixed effects. Significant treatment differences were identified as those with a P value $<.05$ (two-tailed).

Pearson correlation coefficients were calculated to assess the linear correlation between FAW blower particulate emissions (generated downstream of the intake filter) and CFUs detected for each swabbing location (distal, proximal, elbow, motor stack, and combined). The P value represents the two-tailed probability that the Pearson correlation coefficient is equal to 0.

RESULTS

A total of 52 FAW blowers (Bair Hugger, model 505; Arizant Healthcare, Eden Prairie, MN) were sampled in their surgical environment of use (ORs) from 11 hospitals. Only OR-dedicated FAW blowers were sampled. Sampling was conducted in 38 separate ORs, in which FAW blowers were sometimes moved to a common OR for sampling that shared the same central hospital ventilation as the other ORs. The distribution of ambient OR air quality provided by the ventilation system differed greatly by hospital (Figs 3 and 4), with ventilation quality ranging from 0 to 800,000 >0.3-μm particles/ft^3 centered on a median of 8,600 >0.3-μm particles/ft^3; upper and lower quartiles were 130,000 and 3,600 >0.3-μm particles/ft^3, respectively.

Intake filter retention efficiency

The retention efficiencies for the model 200708C (n = 5) and 200708D (n = 5) filters differed significantly,

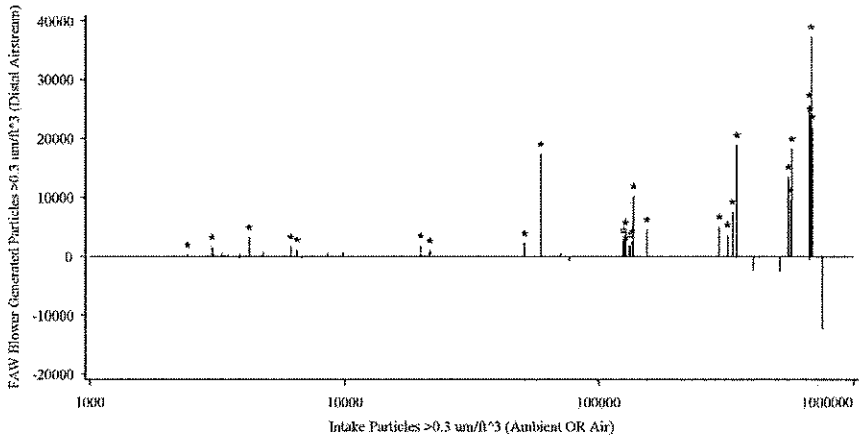

Fig 4. FAW blower distal hose airflow particulate emissions above (or below) expected levels based on the measured efficiency of each filter and intake air particulate levels. *FAW blowers with significant particulate emissions exceeding the expected level ($P < .05$).

with mean reported retention efficiency values of 93.8% and 61.3%, respectively, at an MPPS of 0.2 μm (Fig 2). A visual inspection of both filters revealed a thinner filtration media in the 200708D filter, a difference that was especially apparent when both filter models were held up to a light source.

Intake filter performance in the surgical environment

Of the 52 model 200708C model intake filters that were challenged with OR air, 47 appeared to have consistent efficiencies within the expected range of operation (Fig 3), and 5 sampled in "dirtier" environments appeared to have lowered filtration efficiencies. A linear no-intercept regression model fitted to the data for the 47 intake filters demonstrating consistent performance identified a filtration efficiency of 95% for >0.3-μm particles as the best fit.

FAW blower-generated particles

Distal hose end air stream particle emissions were well above what would be expected for the majority of FAW blowers (n = 30) based on reported intake filter performance. Deviations from expected distal particle emissions for each FAW blower—a quantity based on measured intake filter performance and distal particle emissions for each individual unit—revealed that 58% of FAW blowers were generating significant levels of >0.3-μm particles, up to 35,000 particles/ft^3 downstream of the intake filter (Fig 4). The magnitude of FAW blower particle generation was loosely correlated with ambient OR air particulate concentrations.

FAW blower air path colonization

Air path swabs from FAW blowers revealed the presence of viable microorganisms in 92% of the blowers (Fig 1), with the heaviest growth reported on the internal air path surfaces of the distal hose end (Fig 5). Isolates of *S aureus*, CoNS, and MRSA were detected inside 13.5%, 3.9%, and 1.9% of the FAW blowers, respectively. Pearson correlation coefficients indicated a lack of correlation between blower-generated particles and internal levels of microbial colonization for the combined measurement ($P = .09$) as well as all individual swab locations (distal, $P = .09$; proximal, $P = .31$; elbow, $P = .26$; motor, $P = .99$). Microbes were detected on the nonspecific growth medium for a small proportion of control samples (9%); all microorganism-specific control samples were negative.

DISCUSSION

Our results suggest that popular FAW devices in current use are of questionable design with regard to preventing airborne contamination emissions into the OR and possibly the surgical field. Inadequate FAW blower intake filtration (93.8% for the model 200708C filter and 61.3% for the model 200708D filter) resulted in an internal buildup of microbial contamination within the majority of FAW blowers (92%) on inaccessible air path surfaces. The majority of FAW blowers (58%) also were found to be internally generating airborne contamination downstream of the protective intake filter. This might have been related to the release of built-up contaminants acquired during previous periods of use in environments with elevated levels of ambient airborne contaminants. This is the first study focusing on

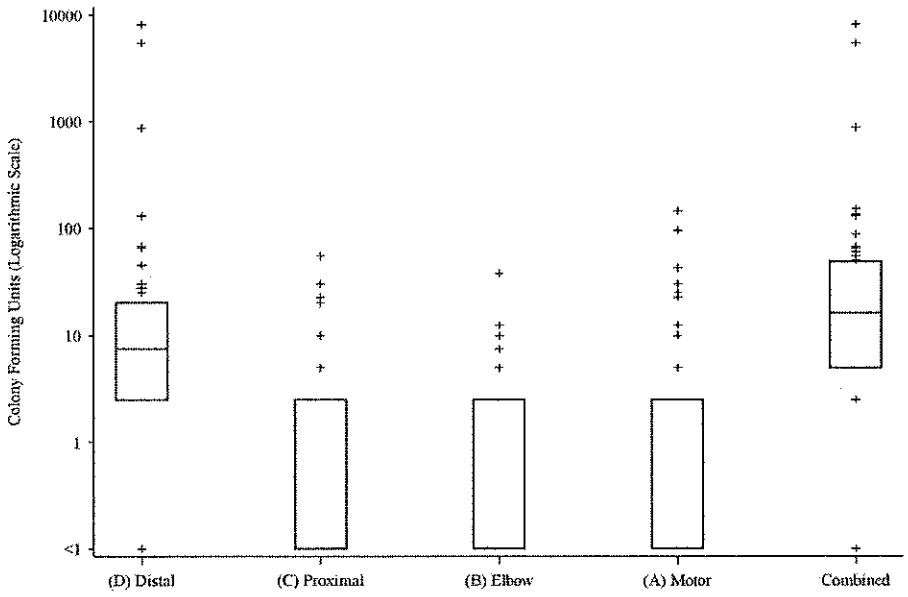

Fig 5. Number of CFUs detected by sampling location, reported as 25th, 50th, and 75th quantiles with marked outliers.

assessing FAW blower intake filter performance and its relationship to FAW blower-generated airborne contamination.

We felt that it was important to characterize the intake filter separate from the FAW blower, given that previous research identified elevated levels of contamination emission from a number of FAW blowers,[15] but the source of this contamination could not be conclusively identified as being downstream of the intake filter. By characterizing the performance of each FAW blower intake filter in its environment of use (the OR), we were able to determine the expected particle emissions from FAW blowers and isolate emissions in excess of this expected value as being introduced downstream of the intake filter within the FAW blower. However, this study was limited in its ability to identify the exact composition of these emitted contaminants, because we identified only selected microorganisms through swabbing and did not collect particulate samples for assessment through microscopy. Nevertheless, previous research, reported intake filter retention efficiencies, and swabbing results provide some general information regarding the source of such contaminants.

Previous studies of the size distribution of airborne contaminants upstream and downstream of FAW blowers concluded that air leaks on the intake side were an unlikely source of contamination.[15] This leaves the wear-and-tear of moving components or the release of built-up contaminants as the most likely sources. The disintegration of moving components is an unlikely source, given that the generation of contamination was not uniform for blowers with similar internal components. This trend toward nonuniformity is apparent in Figure 4 if several relationships are considered. First, FAW blowers with similar levels of intake particulate challenge typically belong to the same hospital. Second, these FAW blowers within a single hospital generally come from the same manufacturing lot and thus have similar internal components. Finally, based on intake particulate challenge results, these groups of blowers from similar lots would be expected to exhibit uniform trends of contamination generation. This correlation is not apparent in Figure 4, however. In contrast, the release of built-up contaminants appears to be a probable cause based on reported FAW blower intake filter retention efficiencies.

All of the FAW blowers evaluated in the OR from this sample population used the model 200708C intake filter, which had a reported retention efficiency of 93.8% when challenged by a specific size of particulate (0.2 μm). In addition, performance data suggest that most of the 200708C filters performed near or within specifications in the OR when challenged with ambient air (95% at >0.3 μm). However, this level of intake filtration implies that approximately 5%-7% of ambient airborne contaminants pass through the intake filter and into the FAW blower. These airborne particles (both viable and nonviable) are likely to reversibly attach to the FAW blower's internal plastic air path surfaces, particularly because plastic surfaces tend to develop an attractive static charge in the presence of a particulate-laden airflow.[30]

As such, the nature of contaminants contained in the FAW blower is likely to depend on both the past and current environments of use. The typical location for FAW

blowers in the OR tends to be near the floor by the head of the operating table. Movements of the surgical staff and patient have been shown to generate large quantities of desquamated skin cells, as much as 10% of which have been shown to carry viable microorganisms.[9,31] These shed skin cells have a wide particle size distribution, extending well below 5 μm due to flake fragmentation;[32,33] thus, a large portion of these skin cells are small enough to become buoyant and follow the downward nature of the laminar air flow toward the FAW blower intake. The efficiency of the intake filter suggests that a large number of these potentially pathogen-carrying cells could penetrate the filter and build up on the FAW blower's internal air path surfaces. This mechanism of airborne skin cell "seeding" is a likely explanation for the 92% internal colonization rate. This is further supported by the finding that approximately 15% of reported isolates were skin-specific organisms, namely *S aureus* and CoNS. In addition, FAW blowers often are moved between clean-air OR environments and the recovery room, a practice that might exacerbate the airborne contamination to which these FAW blowers are exposed. This relationship between environmental exposure and the degree of FAW blower contamination generation is illustrated in Figure 4, where higher degrees of contamination generation in ORs with higher ambient particulate levels.

The concept of "seeding" also presents the possibility of microbe growth and aerosolization from internal FAW blower surfaces. Deposited contaminants may act as the nutrient source for sustaining microbe growth. However, Pearson correlation coefficients demonstrated no conclusive relationships between detected CFU counts and emitted contaminant levels, suggesting that a large portion of emitted contaminants were nonviable in nature. Our results warrant future research into this matter.

Nevertheless, relevant clinical risks are related to the potential release of these airborne contaminants from FAW blowers in the vicinity of the surgical site. Although our findings do not establish a direct link between FAW and increased SSI rates, they do raise awareness of the potential risks associated with FAW use. Further, our results and those of others[15-18] demonstrate appreciable microbial contamination on the internal air path surfaces of FAW blowers, consisting of common pathogenic isolates (*S aureus*, CoNS, MRSA) that are typically involved in superficial and deep SSIs.[11] These isolates, as free-floating bacteria, are commonly found in ORs and have a particle size range of 0.5-4 μm,[34] which corresponds to the size distribution of FAW blower-borne contaminants detected in this study. In prosthetic surgery, all of the identified organisms are associated with appreciable morbidity and mortality, and their presence could lead to the need for revision or removal of an infected prosthetic joint.[35] Moreover, the potential for the mobilization and release of built-up pathogenic contaminants suggests that FAW blowers might increase the risk of cross-contamination between operations; for example, one study implicated FAW blowers as the causative factor in an outbreak of *Acinetobacter baumannii*.[18]

Our results point to 3 primary design inadequacies of FAW blowers that contribute to the buildup and release of contaminants. First, the inaccessible nature of the internal FAW blower air path surfaces prevent regular cleaning and decontamination. This is in contrast to guidelines from the European Union Medical Device Directives, US Food and Drug Administration, and Health Canada regarding reusable medical equipment that either require or recommend manufacturers to offer a means for decontamination.[36-38] Second, current FAW blower intake filtration measures are inadequate to prevent the buildup of microorganisms on internal air path surfaces. Finally, the design of current FAW blowers does not include an outlet filter that could prevent the emission of contaminants into the OR. FAW device manufacturers should be encouraged to redesign FAW blowers such that internal surfaces are accessible for decontamination and that true HEPA filtration (>99.97% at 0.3 μm) is offered as a protective measure at the intake and hose outlet. In the meantime, hospitals and care providers might consider periodic sterilization procedures for reconnectable components of their FAW machines. In addition, the introduction of a new filter (model 200708D) with lower filtration efficiency (61.3%) in popular FAW blower models is of concern.

In conclusion, this study highlights the potential risks of intraoperative surgical site contamination when FAW devices are used in clean OR environments. These risks may be elevated in contamination-sensitive operations, such as prosthetic elective surgery, that demand laminar HEPA airflow ORs. The need to avoid inadvertent hypothermia is now well recognized[39] and is part of the mandatory checklist in the World Health Organization's "Safe Surgery Saves Lives" campaign.[40] Our findings suggest that it would be prudent to add HEPA filtration to the intake and outlet of FAW blowers to reduce the risk of emission and mobilization of contaminants in the OR environment. Alternatively, air-free warming technologies, such as conductive fabric mattresses and blankets,[23-29] that can be easily decontaminated should be considered.

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EXHIBIT DX3

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

Forced-Air Warming Design: Evaluation of Intake Filtration, Internal Microbial Buildup, and Airborne-Contamination Emissions

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Mark C. Albrecht, MStat, MBA, BSME

Forced-air warming devices are effective for the prevention of surgical hypothermia. However, these devices intake nonsterile floor-level air, and it is unknown whether they have adequate filtration measures to prevent the internal buildup or emission of microbial contaminants.

We rated the intake filtration efficiency of a popular current-generation forced-air warming device (Bair Hugger model 750, Arizant Healthcare) using a monodisperse sodium chloride aerosol in the laboratory. We further sampled 23 forced-air warming devices (same model) in daily hospital use for internal microbial buildup and airborne-contamination emissions via swabbing and particle counting. Laboratory testing found the intake filter to be 63.8% efficient. Swabbing detected microorganisms within 100% of the forced-air warming blowers sampled, with isolates of coagulase-negative staphylococci, mold, and micrococci identified. Particle counting showed 96% of forced-air warming blowers to be emitting significant levels of internally generated airborne contaminants out of the hose end. These findings highlight the need for upgraded intake filtration, preferably high-efficiency particulate air filtration (99.97% efficient), on current-generation forced-air warming devices to reduce contamination buildup and emission risks.

Keywords: Airborne contamination, filtration, forced-air warming, operating room ventilation, patient warming.

Forced-air warming (FAW) is widely used to prevent surgical hypothermia. The benefits of preventing surgical hypothermia include reduced blood loss, improved wound healing, reduced duration of hospital stay, improved survival, and reduced rates of surgical site infections.[1] Ideally, the air exhaust from FAW devices should be free of particulate matter and microorganisms since the airflow is often vented near the operative site. To reduce contamination emission risks, FAW devices are equipped with an intake filter, but there is minimal published evidence supporting the performance of the intake filter in regard to (1) protecting the blower's internal air path from a buildup of microbial contamination and (2) preventing the emission of resident airborne contaminants that are drawn into the blower.

Forced-air warming devices employ a 0.2 µm–rated intake filter to prevent the passage of airborne contamination, which consists of all particulate matter suspended in operating theater air. Common forms include microbial-laden dust, desquamated skin, and respiratory droplets.[2] However, the "0.2-µm" rating conveys no information about the quality of the intake filter and instead describes the size of particle with which the filter was challenged. The critical performance parameter is the "filtration efficiency" (ie, how well the filter captures the 0.2-µm challenge particles). Prior research has rated the intake filtration efficiency of legacy FAW devices (Bair Hugger 505, Arizant Healthcare) at 93.8% for an "older" filter model in clinical use (200708C) and 61.3% for a "newer" filter model (200708D) scheduled to replace the older filter in clinical use.[3] This same research found high levels of internal microbial buildup and contamination emissions from these legacy devices in hospital operating theaters using the "older" 93.8% efficient intake filter.

Relatively little is known about the design of current-generation FAW devices regarding intake filtration efficiency. Therefore, in this study we chose to evaluate the filtration performance of a popular current-generation FAW device (Bair Hugger 750) and sample for contamination emissions and/or internal microbial buildup in a European hospital environment.

Methods

Sampling Procedures and Assessments. Sampling procedures included intake filter efficiency, intake filter performance in the operating theater, generation of airborne contamination by the FAW devices, and microbial colonization of the internal air path surface.

Intake Filter Efficiency. New intake filters were ac-

quired from the manufacturer (Arizant Healthcare) for testing filter efficiency, which was measured by challenging the filters with sodium chloride particulate through a range of monodisperse particle sizes (0.025 to 0.50 µm) at an airflow of 45 cu ft/min. The test schematic used the following: an air supply blower; high-efficiency particulate air (HEPA) filtration at the intake; an atomizer (Quant Technologies LLC); an aerosol neutralizer (model 3077, TSI Inc); an electronic classifier (model 3080, TSI Inc); 2 condensation particle counters (models 3772 and 3782, TSI Inc); and an air velocity meter (Dwyer Instruments Inc).

Filtration efficiency was calculated as the fraction of particles captured by the filter during a 10-minute challenge. Challenge concentrations varied from 85,000 to 1,100,000 particles per cubic foot depending on particle size. The most penetrating particle size (MPPS) is defined as the particle size at which the filter displayed a minimum efficiency.

Intake Filter Performance in the Operating Theater. Twenty-three FAW blowers, in a single hospital in Vienna, Austria, were sampled after-hours in the operating theaters to quantify the performance of the intake filter in the clinical environment. This was measured separately from the FAW blower, using a fixture that challenged the intake filter with ambient air in the operating theater. The fixture consisted of a downstream vacuum (calibrated to draw 1,274 L/min or 45 cu ft/min), a mounting plate, and an internal particle sampling pitot tube downstream of the filter. With the intake filter attached to the fixture and the vacuum running, laser particle counts of a 0.1-cu ft sample volume (Particle Measuring Systems) were taken upstream and downstream of the intake filter. Three samples were taken at each location.

Intake filter performance in the operating theater environment was assessed as the fraction of particles 0.3 to 0.5 µm, 0.5 to 5.0 µm, and greater than 5.0 µm captured by the intake filter.

Generation of Airborne Contamination. The filters were replaced, and these same 23 FAW blowers were sampled for generation of airborne contamination, which was determined by comparing observed particle counts in the airstream exiting the FAW blower with what would be predicted based on the measured filtration efficiency of each intake filter. Specifically, we measured particle counts greater than 0.3 µm in the intake and distal airstreams (3 0.1-cu ft samples each).

Afterward, filter particle concentrations were calculated for each FAW blower by (1) computing the average particle concentration greater than 0.3 µm in the intake airstream and (2) multiplying the average intake airstream particle concentration by the fraction of particles greater than 0.3 µm removed by the intake filter (as observed during intake filter performance testing). FAW internal contamination generation was identified by comparing distal airstream particle concentrations with after-filter particle concentrations, which should be the same in the absence of contamination generation.

Internal Air Path Microbial Colonization. For these same 23 FAW blowers, microbial colonization of the internal air path surface was assessed via swabbing. A 10-cm^2 area inside (1) the "distal hose" end and (2) inside the FAW blower directly upstream of the hose connection ("elbow") were sampled. Control swabs were also taken and sent to the microbiology laboratory in a blinded fashion with the active samples. Microbiological culturing and analysis were performed by the in-hospital laboratory.

Colony-forming units (CFU) per swab were assessed by the following process. Swabs were transported to the laboratory in 5 mL of diluent and vortexed in the transport container. One mL of diluent was pipetted in duplicate into Petri dishes, and 25 mL of molten 45°C tryptic soy agar was added to form a nonselective growth medium. The dishes were incubated for 48 to 72 hours at 36.0 ± 0.1°C. Each individual colony was enumerated as a single CFU, and reported values per swab represent the average of the 2 dishes. The CFUs for the locations of distal hose and elbow were those detected from a single swab used at each location. Combined CFUs per FAW blower were the sum of both locations.

The presence of specific microorganisms was also assessed for each FAW blower by pooling the remaining diluent from both locations. This diluent was enriched, incubated (for 24 hours at 36.0 ± 0.1°C), and then tested for the following: mold and *micrococci* using Gram staining; *Staphylococcus aureus* and coagulase-negative *staphylococci* (CoNS) using Gram staining and catalase identification; and methicillin-resistant *S aureus* (MRSA) using oxacillin for test sensitivity.

Statistical Analysis. Forced-air warming blowers having significant internal contamination generation were identified using a variance weighted analysis of covariance (ANCOVA) model, with the difference between distal and after-filter particle concentrations as the response. Predictors included intake particle concentration as a covariate; and blower serial number and treatment (filter isolated or filter on FAW blower) as fixed effects. Significant differences were identified as those having *P* values less than .05 (2-tailed) after Bonferroni correction for familywise error rates (n = 23 comparisons). Given that this was an observational study, sample sizes were not determined a priori.

Pearson correlation coefficients were calculated to assess the linear correlation between FAW blower contamination generation (difference between distal and after- filter particle concentrations) and CFUs detected at each swabbing location. *P* values represent the 2-tailed probability that the Pearson correlation coefficient is equal to zero.

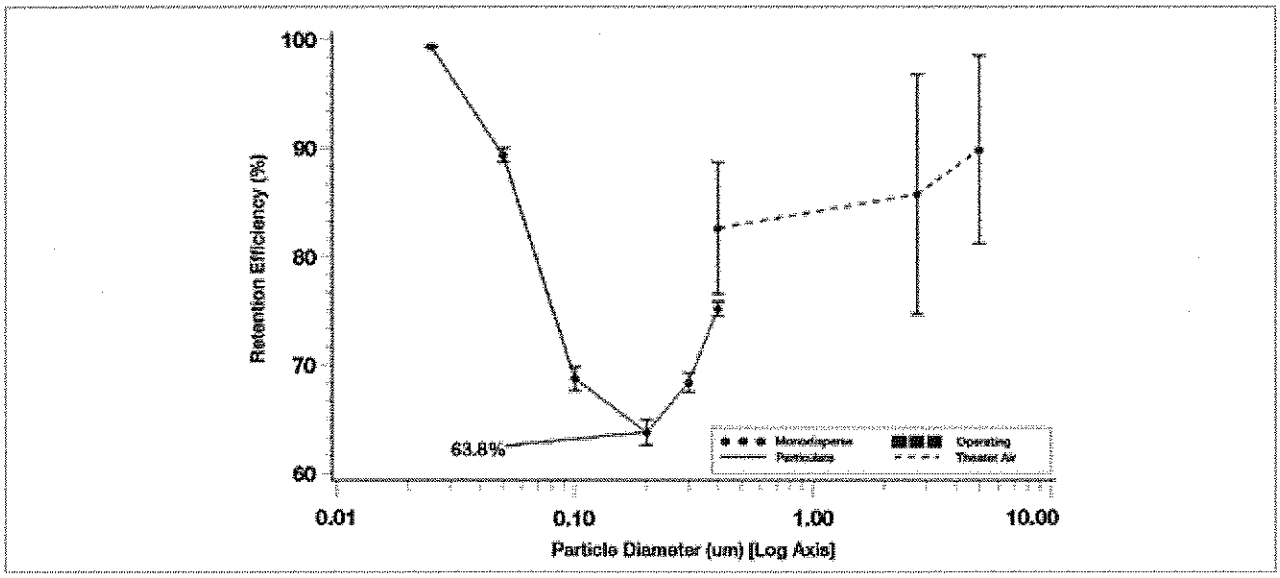

Figure 1. Mean Retention Efficiencies (± standard error of mean) for Intake Filter When Challenged With Operating Theater Air (n = 23) and Monodisperse Sodium Chloride Particulate (n = 5)[a]

[a] Solid line indicates monodisperse sodium chloride particulate; broken line, operating theater air. Disparities in retention efficiency between the 2 test methods at similar particle sizes (in micrometers) arise from differences in both the type of challenge particulate used and particle size classification methods. Intake filter was model 750093D (Arizant Healthcare).

Results

Intake Filter Retention Efficiency. The mean efficiency for intake filter model 750093D (n = 5) was found to be 63.8% at the MPPS of 0.2 µm (Figure 1) using a test method in accordance with ventilation industry standards.

Intake Filter Performance. To confirm that the intake filter was performing within specification in its environment of use, intake filters (model 750093D) from 23 FAW blowers were removed and challenged with operating theater air. Efficiencies for these filters in the operating theater were added to the plot of reported filtration efficiencies formerly determined by heating and ventilation standards (see Figure 1). Retention efficiencies were plotted for each particle channel size on the laser particle counter (0.3 to 0.5 µm, 0.5 to 5.0 µm, > 5.0 µm) as the center of that corresponding channel size when possible (0.4 µm, 2.75 µm, and 5.0 µm, respectively). Slight disparities in retention efficiency between the 2 test methods at similar particle sizes arose from differences in both the type of challenge particulate used and particle size classification methods. As such, the detection of only marginal differences in filtration efficiency at similar particle sizes between the 2 test methods suggests that the intake filters were performing within specification in their environment of use.

Airborne Contamination Emissions in the Operating Theater. Twenty-three FAW blowers (Bair Hugger 750) were sampled in their dedicated operating theaters. The distribution of ambient air quality provided by the ventilation system in the operating theater was relatively uniform. Particle counts ranged from 150 to 39,000 particles greater than 0.3 µm/cu ft centered on a median of 4,400 particles greater than 0.3 µm/cu ft; upper and lower quartiles were, respectively, 7,000 and 1,800 particles greater than 0.3 µm/cu ft.

Distal hose end air stream particle emissions were well above what would be expected for most FAW blowers (n = 22) based on intake filter performance (Figure 2); 96% of FAW blowers were generating significant levels of contamination greater than 0.3 µm in size. These FAW blowers were generating up to 110,000 particles per cubic foot downstream of the intake filter, which at an airflow of 1,274 L/min (45 cu ft/min) translates to 82,500 particles per second being emitted from the FAW blower hose end. Moreover, 70% of the FAW blowers had hose-end airflows with higher contamination levels than in intake airflows.

Internal Air Path Microbial Colonization. Air path swabs revealed the presence of viable microorganisms in 100% of FAW blowers (Table), with the heaviest growth reported on the internal air path surfaces of the elbow (Figure 3). Isolates of coagulase-negative *staphylococci* (CoNS), mold, and *micrococci* were detected inside 74%, 26%, and 9% of FAW blowers, respectively. Pearson correlation coefficients indicated a general lack of correlation between blower-generated particles and internal levels of microbial colonization for the combined CFU measure (P = .23) and individual swab locations. Microbes were detected on a high percentage of the control samples in nonspecific growth medium control samples (50%). However, the degree of colonization in the controls was much less than in sampled FAW devices, approximately 2% (see Figure 3).

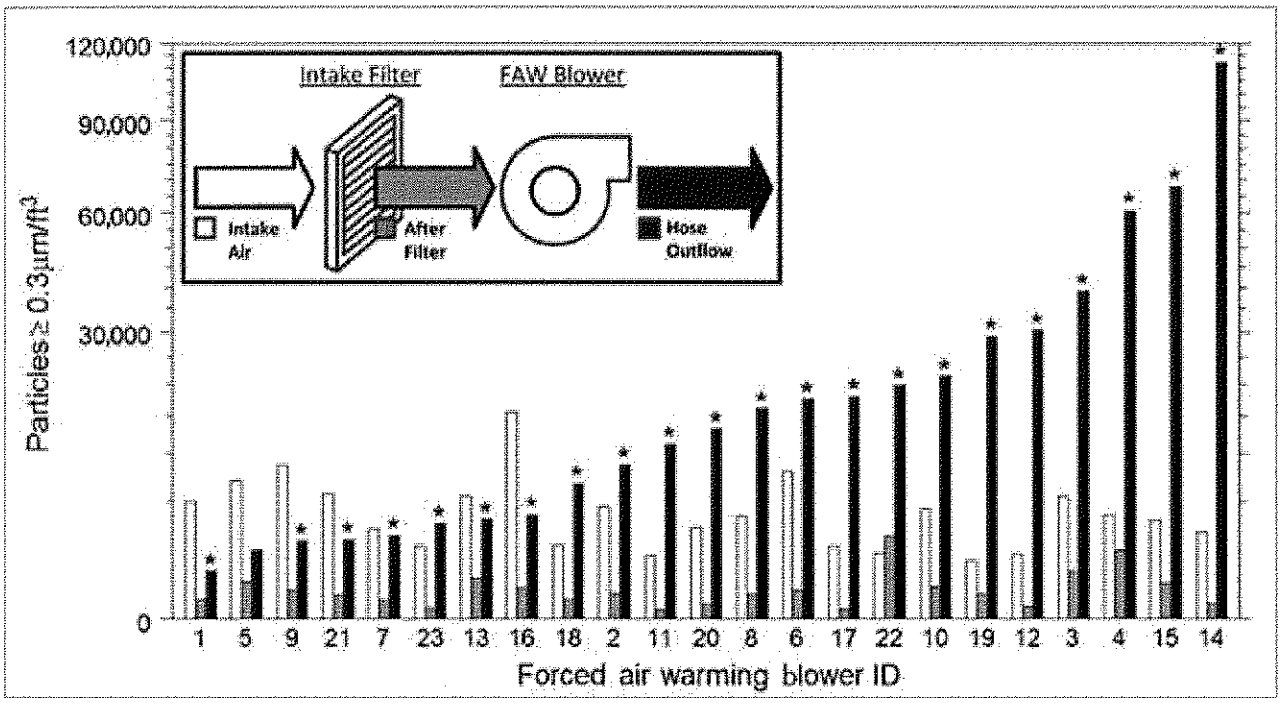

Figure 2. Airborne Particle Concentrations of Intake Air, After Filter, and Hose Outflow[a]
Abbreviations: FAW, forced-air warming; ID, identification number.
[a] 0.3 µm/cu ft = .
* Indicates significant elevations ($P < .05$) in hose-outflow particle concentrations vs after-filter particle concentrations.

Discussion

The results of this study suggest that inadequate FAW device intake filtration (63.8% efficient) led to a significant buildup of internal microbial contamination in the FAW blowers sampled. This buildup occurred on inaccessible air path surfaces that could not be cleaned. Most FAW blowers were also found to be internally generating airborne contamination downstream of the intake filter. This contamination was emitted into the operating theatre through the FAW hose-end airflow.

Similar research was undertaken in the United States on legacy FAW devices (Bair Hugger 505) having a substantially higher intake filtration efficiency (93.8%).[3] The reduced filtration efficiency (63.8% efficient) exhibited by current-generation FAW devices in the present study appeared to result in substantially higher levels of internal air path colonization and airborne contamination emissions. Furthermore, the composition of identified microbes in current-generation FAW blowers favored pathogens associated with surgical site infection (76% detection rate for CoNS), whereas the detection rate for such pathogens was less in legacy FAW blowers (17% combined detection rate for S *aureus*, CoNS, and MRSA). Differences in surgical practices and environmental factors between US and European hospitals may have contributed to this observed discrepancy. However, it is difficult to overlook the observed reduction in intake filtration efficiency as the primary factor responsible for greater internal colonization and emissions.

Microorganism detection by internal air path location, % of FAW blowers	
Distal hose end	96
Elbow	95
Combined (either location)	100
Specific organism detection, % of FAW blowers	
Staphylococcus aureus	0
Coagulase-negative *S aureus*	74
Methicillin-resistant *S aureus*	0
Mold	26
Micrococci	9
Pearson correlation of FAW contamination generation and CFUs by site, coefficient (*P* value[a])	
Distal hose end	0.19 ($P = .39$)
Elbow	0.25 ($P = .26$)
Combined (either location)	0.26 ($P = .23$)

Table. Detection of Microorganisms and Pearson Correlations Between Forced-Air Warming (FAW) Blower–Generated Particles and Colony-Forming Units (CFU) by Swab Location
[a] *P* values represent the probability that there is no linear correlation.

Many, perhaps most, physicians assume that a "0.2 µm–rated" intake filter removes all particles greater than

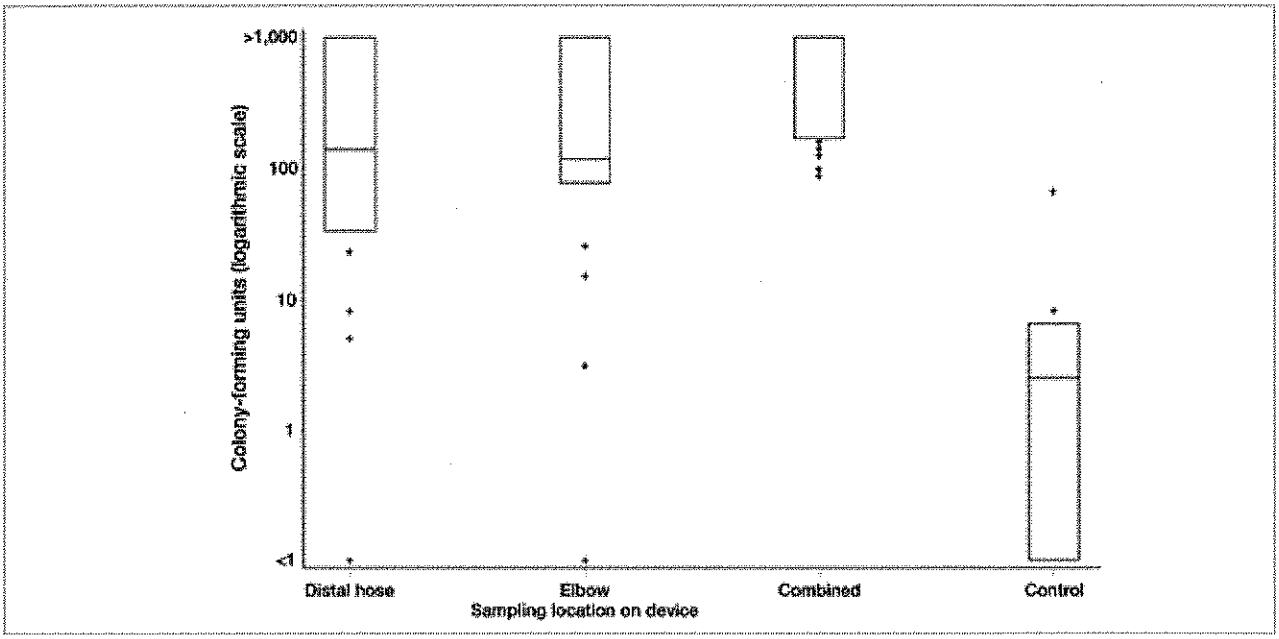

Figure 3. Detected Colony-Forming Units by Forced-Air Warming Device Sampling Location and Control Samples, Reported as 25th, 50th, and 75th Percentiles With Marked Outliers

0.2 µm using a straining action with pore sizes equal to 0.2 µm. For example, the discussion from one of the more commonly cited references on this subject matter states: "the floor mounted blower used in the present study is designed with a 0.2-µm filter at the air intake, this size being much smaller than the average size of bacteria-carrying particles (20 µm)."[4] In fact, the "0.2-µm" rating means quite the opposite and instead specifies the particle size that most easily penetrates the intake filter (see Figure 1). Depth filters, such as those used by FAW devices, are not constructed to have a defined pore size, but instead are a matted layer of fibers. The mechanisms of filtration are much more complicated than a simple straining action and principally rely on a particle's random motion intersecting a fiber within the filter.[5] Thus, the use of a 63.8% efficient, 0.2 µm–rated intake filter does not prevent the passage of contaminants greater than 0.2 µm through the filter and into the FAW blower. Instead, contaminant penetration is dependent on filtration efficiency at a given particle size, where filtration efficiency tends to be higher for particles larger than the 0.2 µm MPPS. This dependency explains why the intake filters were shown to be 87% and 89% efficient for particles 0.3 to 0.5 µm and 0.5 to 5.0 µm in size, respectively. Yet, this level of intake filtration implies that approximately 10% of the larger ambient airborne contaminants pass through the intake filter and into the FAW blower.

As such, the nature of the internal contaminants is likely to depend on both the past and present usage environments. The typical location for FAW blowers in the operating theater tends to be near the floor by the head of the operating table. Movements of the surgical staff and patient have been shown to generate large quantities of desquamated skin cells, of which as many as 10% have been shown to carry viable microorganisms.[6] Studies have shown these shed skin cells to have a wide particle size distribution extending below 5 µm because of flake fragmentation.[7] These skin cells are affected by gravity and the downward nature of the laminar airflow, both of which direct them toward the floor and the FAW blower intake. The reduced efficiency of the intake filter suggests that these pathogen-carrying cells penetrate the filter and buildup on the FAW blower's internal air path surfaces. This mechanism of airborne skin cell "seeding" is a likely explanation for the high degree of internal colonization, which is supported by the findings that 74% of reported isolates were skin-specific organisms (CoNS). Furthermore, the swabbing results of other studies[3,8-11] have found microbial contamination on internal air path surfaces consisting of skin isolates associated with surgical site infection (*S aureus*, CoNS, MRSA).[2]

As a whole, these findings question an important and common assumption about the design of FAW devices, namely that "all forced-air warming [blowers] include filters that essentially eliminate bacteria in the heated air."[12] Supporting evidence for such a statement was based on evaluations of overall operating theater contamination with instruments such as settle plates.[4,13,14] Only recently has the performance of FAW intake filters been directly studied.[3] However, for a direct risk to be present, the exhausted FAW airflow would need to reach the surgical site. It is presently unknown whether this happens, because surgical drapes may act as a barrier. Moreover, the coverlet may act as a low-efficiency microbial filter.[9]

Both of these issues warrant additional research.

This study has several limitations. First, we were unable to locate service/maintenance records indicating that the intake filters were regularly replaced. However, we did not detect any major degradation in filtration performance for 22 of the 23 intake filters that were individually tested in the operating theater (see Figure 2). Furthermore, depth filtration media tend to offer improved filtration as they load up[5]; thus, the concern that the filters were performing under specification appears to be minimal. Second, we did not sample for microorganisms in the hose-end airflow and instead relied on particle counting to quantify airborne contamination emissions. Our assessments of clinical risk assume that a portion of the emitted contaminants are microbial in nature, an assumption that is supported by prior research.[9] Last, we did not track hospital infections, nor did we study the association between FAW contamination generation/emission and hospital infection rates; the aims of this study were limited to evaluating the design of FAW equipment in regard to prevention of contamination buildup and emissions.

To address the identified design deficiencies, manufacturers should redesign FAW blowers to allow for regular cleaning and decontamination in accordance with governmental guidelines for reusable medical equipment.[15-17] Second, inlet filtration could be upgraded to HEPA quality (99.97% efficient) to prevent microbial ingress. Last, the addition of a filter at the distal hose end would be of benefit in reducing airborne contamination emissions. Outside these suggested design changes, the perioperative surgical care team should be aware of the apparent cross-contamination risks of moving FAW equipment between clean and dirty environments. Presumably, FAW equipment used during clean surgery should be confined to its dedicated operating theater of use.

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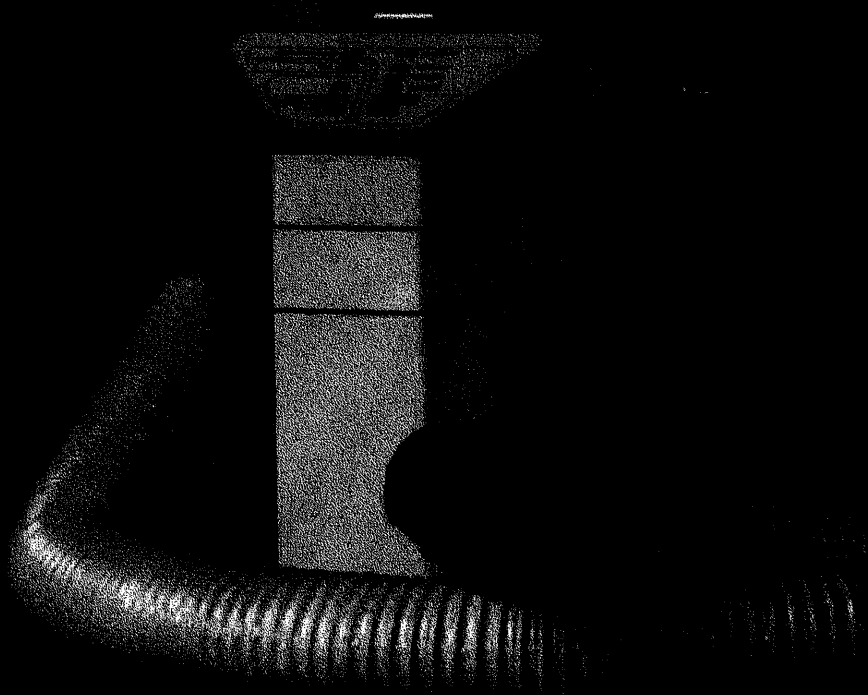
EXHIBIT DX4

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

Blowing Air Is Risky



... now there's an [air-free] alternative.

"RESERVOIRS OF INFECTION"

Recent studies show that the air-flow paths of Bair Hugger™ blowers are frequently contaminated with bacteria.[2,3] These units blow many millions of germ-sized particles into the operating theatre each hour. No wonder a Department of Public Health in the U.S. called Bair Hugger units **"reservoirs of infection."**[5]

Contaminated Air is Blowing from the Unit

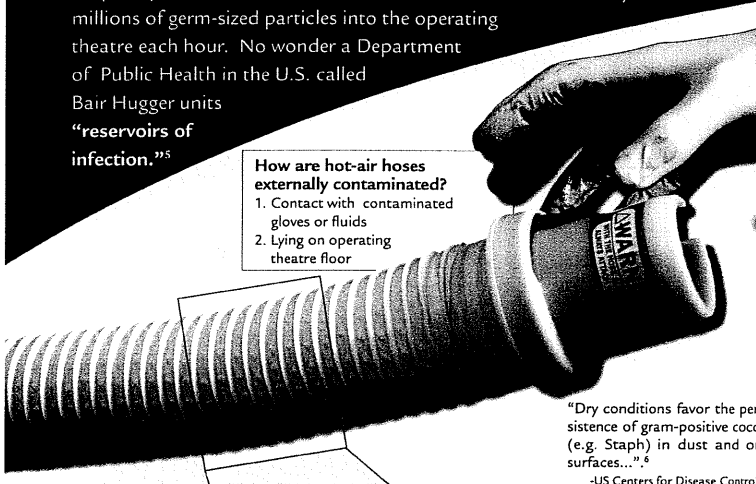
Particle counters have measured more than 50 million germ-sized particles per hour blowing from Bair Hugger units into the operating theatre.[4]

Fifty million particles? Where do they come from?

Blowers suck in clean air and pass it through a .2 micron filter—and still they blow millions of germ-sized particles into the operating theatre. Therefore, most of these particles must be originating from *inside* the blower and hose.

How are hot-air hoses externally contaminated?

1. Contact with contaminated gloves or fluids
2. Lying on operating theatre floor

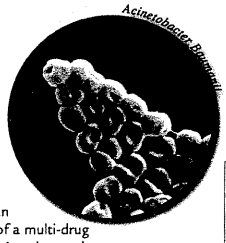


What are these 50 million particles?

Not all of the particles are bacteria, but bacteria can be cultured from both the air and hoses of many hot-air warming units. There should not be any particles, much less germs, blowing from the hose.

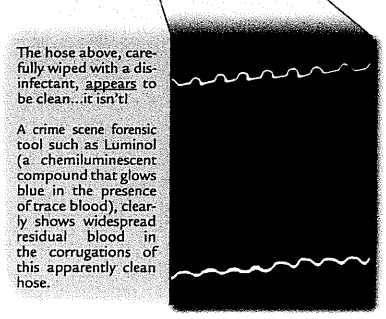
Germ colonies can be cultured by swabbing various locations within the unit or hose, or even by impacting the air blowing from the hose onto a culture plate.[3]

"Dry conditions favor the persistence of gram-positive cocci (e.g. Staph) in dust and on surfaces...".[6]
-US Centers for Disease Control



Infection Control and Hospital Epidemiology reported an outbreak of a multi-drug resistant *Acinetobacter* that was traced directly to the inside of a Bair Hugger machine.[2]

Despite reports such as this, the manufacturer does not offer a protocol for cleaning the insides of Bair Hugger blowers or hoses.[7]



The hose above, carefully wiped with a disinfectant, appears to be clean...it isn't!

A crime scene forensic tool such as Luminol (a chemiluminescent compound that glows blue in the presence of trace blood), clearly shows widespread residual blood in the corrugations of this apparently clean hose.

Can hot-air hoses be cleaned? NO!

Routine wiping does not remove contaminants from the valleys of the hose. The creases within the 180 corrugations of a 7-foot hose are nearly impossible to clean.

All non-disposable equipment in the operating theatre must be cleaned—especially after exposure to blood, bacteria, and bodily fluids. Non-cleanable equipment is simply unacceptable.

Are airborne particles dangerous?

"The link between post-operative infection and theatre air quality has been well established."[8]
-UK Hospital Infection Society

A single bacterium can infect a new joint implant.[9]

AIRBORNE CONTAMINATION
by blowing hot air

TO CONTAIN MRSA, AIRBORNE TRANSMISSION MUST BE PREVENTED

Leading experts in microbiology from Oxford, Cambridge and the University of London highlighted the MRSA problem in a letter to the *Times* of London. MRSA infections, said these experts, are far more likely to result from airborne transmission than from skin contact or equipment contact. **"Staphlococcus aureus [including MRSA] spreads on millions of tiny skin particles, shed by carriers, drifting in the air...." "To be truly effective, measures to contain MRSA must block airborne transmission."**[10]

- Blowing air through a contaminated warming unit may cause bacterial colonies to become airborne.
- Blowing air from a forced-air blanket across the skin may also cause skin particles to become airborne, spreading them into the operating theatre. Infectious agents—such as MRSA—can independently float in moving air or on "rafts" of dead skin particles.[11]

"We conclude that these warming devices* are a potential source of nosocomial infection."[3]

*Bair Hugger and Warm Touch®[1]

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Rev A

EXHIBIT DX5

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

Kentucky Epidemiologic Notes & Reports

Cabinet for Health and Family Services
Department for Public Health
Division of Epidemiology and Health Planning

Volume 42 Number 2 March 2007

Acinetobacter Infections among Hospitalized Patients in Kentucky – 2006

Emphasis on environmental cleaning and isolation precautions may prevent future outbreaks

Suzanne Beavers, MD, CDC Epidemic Intelligence Service Officer, Kentucky Department for Public Health

CDR Doug Thoroughman, Ph.D., CDC Career Epidemiology Field Officer, Kentucky Department for Public Health

Background

Acinetobacter baumannii is a gram negative rod commonly found in the environment, including the soil, food, and water. Although *Acinetobacter* infections caused only about 7% of Intensive Care Unit (ICU) pneumonias in 2003, they are an increasingly common cause of nosocomial and ICU pneumonia (1). In September 2006, two Kentucky hospitals in different communities independently reported *Acinetobacter* outbreaks to the Kentucky Department for Public Health (DPH) within one week of each other. This report describes the outbreak investigation performed at these two facilities.

Investigation Methods

On September 29, 2006, DPH received notification of an *Acinetobacter* outbreak among patients in Hospital A. On October 3, the Centers for Disease Control and Prevention (CDC) notified DPH of a cluster of patients in a second facility (Hospital B), after being contacted directly by Hospital B infection control staff (CDC refers such state-based inquiries back to the State health department). An increase in case-patients from a baseline of approximately 1-2 per month to approximately 15 per month was reported for the months of August through October in Hospital A, and April through October in Hospital B. Patients were diagnosed with *Acinetobacter* based on wound, blood, sputum, urine, or bone culture obtained after a change in the patient's clinical status occurred.

A total of 102 people were confirmed positive at the two facilities by clinical culture (30 in Hospital A and 72 in Hospital B). A CDC investigation was requested by DPH to provide additional personnel to assist with the large workload that would be generated by chart reviews, infection control compliance assessments, environmental evaluations, and lab testing inherent in a hospital investigation of this nature. Suzanne Beavers, MD, (the author of this article and Kentucky's Epidemic Intelligence Service (EIS) officer) began the investigation in early October, 2006 and subsequently led a team of four CDC investigators who arrived on October 30th. The primary goals of the investigation were to perform a case-control study to find risk factors associated with *Acinetobacter* infection, to examine infection control practices at the hospitals involved, and to look for ways to decrease transmission possibilities and incidence of infection at the two facilities.

A case was defined as a patient hospitalized during August 1-October 31, 2006 (Hospital A) or April 1-October 31, 2006 (Hospital B) who developed a positive culture for *Acinetobacter* on a clinical specimen. Patient charts were reviewed in order to evaluate potential risk factors such as admitting service, unit on admission, past medical history, surgeries during hospitalization, and need for ventilation or an invasive intravascular device. A control population was selected from patients without

(Continued on Page 2)

March Notes & Reports.....

Acinetobacter who were hospitalized greater than or equal to the mean length of hospitalization for cases prior to obtaining the first positive culture. Isolation room practices were also observed in order to determine the level of compliance among hospital staff for contact and isolation precautions. In order to evaluate cleaning of high touch areas, a fluorescein compound visible with Wood's lamp was placed in patient rooms. The rooms were checked on subsequent days to determine if the fluorescein compound had been removed by daily cleaning, or cleaning of the room after patient discharge from the room. Environmental samples of high-touch areas in rooms containing patients positive for *Acinetobacter* were also taken.

Results

The mean age of cases was 43 years in Hospital A and 46 years in Hospital B. At Hospital A, 48% of cases were female; 25% of cases were female in Hospital B. The majority of patients (51.7% in Hospital A, 62.5% in Hospital B) cultured positive from a respiratory specimen. During the initial analysis, admission to a surgery service was associated with *Acinetobacter* infection, as was ICU admission. Artificial ventilation was also associated with a positive culture. The majority of patients (81.5% at Hospital A, 70.8% at Hospital B) had multi-drug resistant (MDR) *Acinetobacter* on culture (Figure 1).

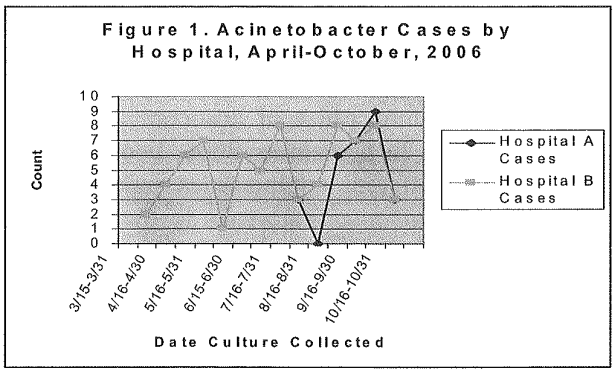
Room observations revealed several instances in both facilities where isolation protocols were violated. Providers were occasionally observed entering the rooms without washing their hands. Providers occasionally entered the room without using barrier precautions such as gowns. Providers also were observed exiting the room without performing adequate hand washing.

Evaluation of the environmental cleaning focused on several high-touch areas in the room. Fluorescein staining was consistently found in high-touch areas in the room after daily cleaning. Fluorescein could also be seen in high-touch areas following cleanings performed after a patient was discharged from the room.

Swabs performed by the hospitals prior to the investigative team's arrival did not reveal a point source of infection or one focus of environmental contamination. However, quantitative environmental testing at the two facilities is ongoing.

Hospital A closed its surgery ICU on the day of the team's arrival for thorough cleaning and decontamination and subsequently closed a second ICU for additional cleaning. In addition, enhanced isolation and decontamination procedures were also instituted throughout the hospital. Hospital A has subsequently reported lower incidence rates since October. Hospital B increased emphasis on following isolation precautions and has used fluroescein to evaluate and increase the importance of cleaning high-touch area, noting a decrease in cases as of February, 2007.

Figure 1. *Acintobacter* cases by hospital, April-October 2006



Discussion

Acinetobacter baumannii is an increasing source of nosocomial infection nationwide. *Acinetobacter* species may cause pneumonia, wound infections, urinary tract infections, or bloodstream infections. Risk factors for *Acinetobacter* infection include recent surgery, admission to an ICU, need for antibiotics during hospitalization, and admission to a ward where other infected patients reside.

Results of the present investigation indicate the need for environmental cleaning staff education on the importance of cleaning high-touch areas. Areas such as bed rails, monitors, and door knobs are likely to be touched by patients and caregivers, and could be a source of spread of the implicated bacte-

(Continued on Page 3)

ria.

Acinetobacter species demonstrate the ability to survive for long periods in the environment. Previous researchers were able to culture *Acinetobacter* from a bedrail nine days after an infected patient was discharged from the room. Therefore, environmental contamination is often an important source of transmission of the organism. Previous outbreaks have found items such as common-use respiratory medications, ventilators, Bair Hugger temperature management units, mattresses, cellular phones, and curtains to be reservoirs of infection. Emphasis on environmental cleaning and observation of isolation precautions are consequently of particular importance in control of *Acinetobacter* outbreaks.

Another factor that has been of importance in the emergence of *Acinetobacter* nosocomial infections is the intrinsic antibacterial resistance of *Acinetobacter* and its ability to quickly acquire new resistance mechanisms. In fact, strains of *Acinetobacter* resistant to all antimicrobials have been isolated. *Acinetobacter* species are readily able to incorporate new genetic material into their DNA. This ability leads to the rapid acquisition of bacterial resistance, even from other types of bacteria such as *Pseudomonas*. The need for frequent use of antimicrobials in intensive care settings is also associated with the rapid acquisition of resistance.

Several methods have been used to control previous outbreaks. When a common source such as a ventilator is identified, cleaning the source properly or preventing patient exposure to the source has been effective in stopping the outbreak. Frequently, however, a common source is not identified. In these cases, increased emphases on environmental cleaning, use of active surveillance, and cohorting patients have been effective in halting outbreaks. Unit closure and environmental decontamination have also been beneficial.

Closing Notes

The outbreak investigations at the two facilities demonstrated the need for reinforcement of isolation precautions and enhanced environmental cleaning. Further analysis of data will continue in order to identify other risk factors and control methods to assist in preventing future outbreaks. Additional work will continue with the hospitals to make recommendations for environmental cleaning as required.

References

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World Tuberculosis Day – March 24

Despite diligent intervention efforts, TB disease remains a global threat

Regina S. Gore, Public Health Advisor/Assistant Program Manager, Kentucky TB Control Program
Melissa Dalton Hopkins, Social Work Consultant/ Health Planner, Kentucky TB Control Program

Condensed from CDC National Center for HIV, STD, and TB Prevention, Division of TB Elimination

Each year, World Tuberculosis (TB) Day is recognized on March 24th. This annual event commemorates the date Robert Koch announced his discovery of the bacillus that causes TB. Around the world, TB programs, non-governmental organizations, and others take advantage of the increased interest and awareness that World TB Day generates concerning the international health threat that the disease presents. It is a day to recognize the collaborative efforts of all countries involved in fighting TB. TB can be cured, controlled, and with diligent efforts and sufficient resources, eventually eliminated.

In 1993, 404 active TB cases were reported in Kentucky, with a case rate of 10.7 cases per 100,000 population. Since 1993, TB case rates have been declining, suggesting that the nation is recovering from a resurgence of TB that occurred in the mid-1980s, and is back on track toward TB elimination. While the decrease in TB case rates is encouraging, the facts about TB continue to be alarming:

- TB continues to kill more people in the world each year than any other infectious disease.
- TB cases continue to be reported in every state.
- Multiple Drug-Resistant TB (MDR-TB) cases

(Continued on Page 4)

continue to be reported in almost every state.

- Extreme Drug-Resistant TB (XDR-TB) has emerged.
- An estimated 10 to 15 million persons in the U.S. are infected with *Mycobacterium tuberculosis*.
- Without intervention, approximately 10% of the 10 to 15 million persons infected in the U.S. will develop TB disease at some point in life.
- Certain other medical conditions increase the risk that a person with TB infection will develop TB disease (e.g. HIV, diabetes mellitus, cancers of the head and neck, jejunoileal bypass, solid organ transplantation, and other immunocompromising conditions).
- HIV infection is the strongest risk factor for progression from TB infection to TB disease. Approximately 50% of HIV-infected persons who become TB infected will develop disease within the first two years of exposure.

Where Are We Now?

TB remains a health threat to people around the world. Among infectious diseases, TB remains the second leading killer of adults in the world, with more than 2 million TB-related deaths each year. In addition to MDR-TB, the emergence of XDR-TB creates a greater and more deadly challenge of this disease. Whereas MDR-TB is drug resistant TB to two or more first line TB drugs, XDR-TB is defined by the World Health Organization (WHO) as TB that is resistant to the two main first line TB drugs, isoniazid (INH) and rifampin (RIF), as well as three of the six main classes of second line drugs. Poor treatment outcomes (patient not responding effectively to treatment) or failed treatment (patient not completing treatment or was lost to follow-up) are the largest contributing factors to the development of MDR-TB and XDR-TB. However, drug resistant strains are transmitted from person-to-person. Until TB is controlled, World TB Day will not be a celebration, but a valuable opportunity to educate the public about the devastation that TB can spread, and how it can be stopped.

TB in Kentucky

Reported cases of TB in Kentucky have reached a historic low. In 2006 there were 84 TB cases reported for a statewide rate of approximately 2.0 cases per 100,000 population. This rate places Kentucky well below the national TB case rate of 5.1 cases per 100,000 population, and below the state objective set in 1999 of reducing the verified TB case rate to 3.5 per 100,000 population. In 2005, the Kentucky TB Control Program reported 124 cases compared to 127 cases in 2004, 138 cases in 2003, and 146 cases in 2002. This case reduction illustrates the hard work and dedication of TB Control staff at the local health departments.

The future of TB Control in Kentucky

The lowering of case numbers is not, however, an indication that the war on TB has been won. Diligent efforts to identify and treat persons with TB infection that are at high risk for developing TB disease is the key to the continued reduction of incidences of TB disease in Kentucky. In addition, ensuring successful treatment outcomes to those with active disease is the main method for preventing MDR-TB and XDR-TB. To date in 2007, there have already been more than 20 active TB cases reported, a high case number for this early point in the year. To prevent resurgence, staff and resource levels must be maintained to allow Kentucky officials to have the tools required to continue working toward elimination of this most persistent disease.

Sexually-Transmitted Disease Update for Kentucky

Advancements in screening programs result in early detection

David Raines, Manager, Kentucky STD Program
Sheri White, Assistant Manager, Kentucky STD Program

Although sexually transmitted disease (STD) rates in Kentucky are not among the highest in the nation, they continue to be the most frequently reported of all communicable diseases statewide. *Chlamydia trachomatis* was the most frequently reported communicable disease in Kentucky in 2005, with 8,351 reports and an attack rate of 201.4 per 100,000 population. Gonorrhea was the second most frequently reported communicable disease in 2005 with 2,935 reports and a rate of 70.8 per 100,000 population. The same trend for these two diseases continued in 2006, as reported chlamydia

(Continued on page 5)

cases increased 7.1% to 8,940 cases. Gonorrhea increased 11.1% with 3,277 reports.

Data released in November 2006 by the Centers for Disease Control and Prevention (CDC) revealed that Kentucky officially ranked 44th nationally in chlamydia and 31st in gonorrhea rates per 100, 000 population in calendar year 2005. *Chlamydia trachomatis* is recognized as one of the most prevalent and potentially harmful STDs today. Men, women and infants are affected, but women bear a greater burden from infection, which is often asymptomatic. Infection in women can seriously compromise present and future reproductive health and may result in ectopic pregnancy, salpingitis, and pelvic inflammatory disease. Neonates of mothers infected with chlamydia and/or gonorrhea may develop an eye infection (opthalmia neonatorum), and neonates of mothers infected with chlamydia could develop pneumonia within the first two months of birth. Many improvements in the laboratory identification of chlamydia and gonorrhea within the past decade have enabled aggressive screening programs to be initiated in each state to identify women with uncomplicated chlamydia and gonorrhea infection. Early detection can enable treatment before complications and debilitating sequela associated with these infections occur. The target population for the screening programs has consisted of women of child bearing age seeking contraceptive, prenatal, STD, cancer screening, and other health services through public and private care facilities. The latest types of tests, known as nucleic acid probes, are more sensitive and specific, and enable the provider to screen patients for both chlamydia and gonorrhea from the same specimen collected by swab from the cervix or from a urine specimen. As a result of the newer testing procedures, there has been a significant decrease in the number of false negative results and an increase in the number of true positive results among persons screened.

Syphilis cases reported in calendar year 2006 totaled 188 compared to 129 cases in 2005. Included in this total were 73 patients with primary or secondary stage disease and 36 patients with early latent stage syphilis disease. The primary, secondary, and early latent stages of syphilis are collectively known as early syphilis because patients have been infected for one year or less and, unless treated, potentially could spread infection to a sexual partner. The 109 patients reported with early syphilis in 2006 was a 34 case (45.3%) increase over 75 early syphilis cases reported in 2005. Included in the 109 early cases were 97 males and 12 females for a male to female ratio of 8:1. Syphilis case reporting is influenced by outbreaks that occur among populations at high risk for acquiring STDs. Over the past four years, a disproportionate number of early syphilis cases have been found in men who have sex with men. In calendar year 2006, 25 Kentucky counties reported one or more patients with early syphilis. Jefferson County reported the most cases with 52 reports, which included 49 males and 3 females. Fayette County had the second highest number of reports with 20 cases, all of whom were males.

Physicians and other healthcare professionals play a critical role in treating and preventing the spread of sexually transmitted diseases. CDC recently released a publication entitled *Sexually Transmitted Diseases Treatment Guidelines, 2006* to assist healthcare professionals in their efforts to diagnose and treat STDs. Requests for the 2006 treatment guidelines can be made through the Kentucky STD Program at (502) 564-4804. The guidelines are also available online at: http://www.cdc.gov/std/treatment/2006/clinical.htm.

Additionally, physicians and healthcare providers are urged to report STDs to their local county health department or to the STD Program at the Kentucky Department for Public Health. The Cabinet for Health and Family Services under 902 KAR 2;020 requires primary, secondary, early latent and congenital syphilis to be reported within 24 hours by fax at (502) 564-5715 or phone (502) 564-4804. Other STDs such as chlamydia, chancroid, gonorrhea, granuloma inquinale, lymhogranuloma venereum, late latent syphilis, and late manifest syphilis are to be reported within five business days. The Kentucky Reportable Disease Form (EPID 200-Rev. May/06) can be accessed online at: http://chfs.ky.gov/providers/ or from the Kentucky STD Program at (502) 564-4804.

KENTUCKY EPIDEMIOLOGIC NOTES & REPORTS
Printed With State Funds
by the
Commonwealth of Kentucky
Cabinet for Health and Family Services
Department for Public Health
275 East Main Street
Frankfort, Kentucky 40621

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Upcoming Articles in *Epi Notes*!

- **Rabies Update**
- **National Infant Immunization Week (April 21-28, 2007)**
- **National Medical Laboratory Professionals Week (April 23-27, 2007)**

EXHIBIT DX6

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

CABINET FOR HEALTH AND FAMILY SERVICES
OFFICE OF THE SECRETARY

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Mark D. Birdwhistell
Secretary

November 13, 2007

Albert Van Duren, M.S.
Director of Clinical Affairs
Arizant Healthcare, Inc.
10393 West 70th St.
Eden Prairie, MN, USA

Dear Mr. Van Duren:

I am writing to clarify some points made in an article I wrote for the *Kentucky Epidemiologic Notes & Reports* in March, 207. In the article I discussed our findings of investigations we performed into outbreaks of *Acinetobacter* at two acute-care hospitals in Kentucky. As you may know, during such investigations we evaluate many factors which may be associated with infection. Therefore, during our investigation we collected data to evaluate whether forced air systems such as Bair Huggers were associated with *Acinetobacter* infection. We did not find an association between *Acinetobacter* infection and Bair Hugger or forced air system use at either facility.

In addition, the Falagas article cited in the paper does not describe forced air systems such as Bair Huggers to be infection reservoirs. The important point of the article and investigation we performed was that a variety of items used during care of ill patients may become contaminated with *Acinetobacter* or other microorganisms. In this investigation, for example, mechanical ventilation was associated with Acinetobacter infection. Therefore, in caring for hospitalized patients, the most important means of preventing infection is to practice good infection control procedures such as hand-washing and environmental cleaning. Conversely, we found no evidence that avoidance of the use of products such as forced air systems would prevent infection with *Acinetobacter*.

I hope this letter answers any concerns you may have regarding your product and the investigation we performed.

Sincerely,

Suzanne Beavers, MD
Epidemic Intelligence Service Officer
Kentucky Department for Public Health

EXHIBIT DX7

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

Christopher Nachtsheim <nacht001@umn.edu>

Publication Factory Continues

1 message

Mark <malbrecht@augbiomed.com> Fri, Jul 9, 2010 at 3:44 PM
To: "Reed Mike (Northumbria Health Care NHS Trust)" <mike.reed@nhs.net>, Paul McGovern <pdmcgovern@gmail.com>
Cc: Scott Augustine <saugustine@augbiomed.com>, Andreas Deibel <adeibel@augbiomed.com>, Keith Leland <kleland@augbiomed.com>, rhumble@augbiomed.com, Christopher Nachtsheim <nacht001@umn.edu>

Paul and Mike,

At this point in time we have 3 completed manuscripts that are ready to be submitted for publication that you are both authors on:

1) An Evaluation Of Filtration Adequacy And Airborne Contamination Emissions From Next Generation Forced Air Warming Blowers. *Target Journal: British Journal of Bone and Joint Surgery*

2) Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Conventional (non-laminar, positive pressure) Operating Room Ventilation Disruption. *Target Journal: US Annals or Archives of Surgery*

3) Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Laminar Operating Room Ventilation Disruption. *Target Journal: Undecided. This is the most complete piece of work on laminar flow disruption and should go to a top tier journal.*

I've already sent both of you articles 1 & 2; article 3 is a new one and, arguably, the best of the three. When I'm in the UK next week I'd like to plan a time (the week of July 19th through 26th) for us to get together, agree on reviews, and submit these articles to 3 appropriate journals. I'd be willing to come up to Northumbria for these purposes.

Also, Dr Andrew Legg has invited you guys to Sheffield hospital the weekend of July 17th and 18th to help with the research effort there. If you are interested the company would be willing to cover your hotel and expenses. Let me know and I'll work to book arrangements. Also, I'm available to conduct further research in Northumbria the dates July 19th -26th. I have the equipment available for your use on those dates. Maybe we could brainstorm some interesting

research ideas.

I'll be available via e-mail this weekend.

Thanks

-Mark

P.S. Paul, I'll work to get some charts together for the 2 studies you sent to me that we can, hopefully, discuss in person.

Mark Albrecht

Augustine Biomedical & Design

6581 City West Parkway

Eden Prairie MN 55344

PH 952-465-3511

3 attachments

Manuscript_European_7-07_tracked.doc
526K

Conventional_Vent_Manuscript_7-2.doc
299K

Manuscript_Laminar_7-9.doc
355K

EXHIBIT DX8

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions

MDL No.
15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

MARK ALBRECHT

VOLUME 2

Minneapolis, Minnesota

Saturday, November 12th, 2016

Reported by:
Amy L. Larson, RPR
Job No. 115236

ALBRECHT

So, "The doctors that do our research," the Paul -- that's Paul McGovern and Mike Reed?

A. Among others. But, yes, we have definitely given them paid support to work with them on research products.

Q. And the, "Publication factory that continues," e-mail, you tell Paul and Mike, "At this point we have three completed manuscripts that are ready to be submitted for publication that you are both authors on," right?

A. Okay.

Q. And you list three documents, right?

A. I see that.

Q. You say, "I've already sent both of you articles 1 and 2. Article 3 is a new one and, arguably, the best of the three." Do you see that?

A. Okay.

Q. How were -- how is it that you were sending them an article that was new that they were coauthors on?

A. It was probably a start of a draft as a

ALBRECHT

placeholder for us all to work from, it may have been, or it may have had some input or may have been other manuscripts that have been rehashed together to form a more cohesive story.

Q. You were the primary author of -- of these studies, right?

A. Not true. I was the person that did the engineering studies, I'm the person that did a portion of the statistics under oversight from others.

Q. You -- you did the drafting and sent it to other people for review, right?

MR. ASSAAD: Objection to form, asked and answered.

THE WITNESS: No. I would construct parts of these and then we'd work as a team to collaboratively figure it out.

BY MR. COREY GORDON:

Q. Well, so what was -- where was the publication factory?

A. Where was the publication factory?

Q. Yeah.

A. That refers to the fact that we've got three

ALBRECHT

articles that we're targeting clinical journals with, and that's a point of pride, that we can produce research at a rate like that.

Q. Okay. Now drop down to the bottom of Exhibit 31 --

A. Okay.

Q. -- where you say, "Also, Dr. Andrew Legg has invited you guys to Sheffield Hospital the weekend of July 17th and 18th to help with the research effort there. If you are interested the company would be willing to cover your hotel and expenses." Do you see that?

A. Yeah.

Q. Do you know, first of all, if either Paul McGovern or Mike Reed took you up on that offer and went to Sheffield and --

A. I'm trying to remember.

Q. -- helped with Dr. Andrew Legg's research effort?

A. I don't recall them being there.

Q. You were there though, right?

A. I was for part of it.

ALBRECHT

Q. Okay. Anyone else from the Augustine company there that you can recall?

A. No.

Q. Who else was there -- who else participated in the research effort that you're referring to there?

A. Which one? The Sheffield one?

Q. Yup.

A. That would be myself and Dr. Andrew Legg. And they look the data and they made a manuscript anova with -- really, without my involvement and went a separate path.

Q. And when you say they took the data, what -- what -- strike that. What --

A. We lended [sic] them a study kit to work with.

Q. What do you mean by study kit?

A. Equipment.

Q. What kind of equipment?

A. Airflow measurement devices.

Q. So you just -- did you just drop them off or did you actually participate in doing the measurements?

A. Participated in some.

EXHIBIT DX9

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

From: Mark <malbrecht@augbiomed.com>
To: 'Mark Litchy' <mark@ctassociatesinc.com>;'Robert Gauthier' <rlgauthier@comcast.net>;'David Leaper' <profdavidleaper@doctors.org.uk>;'Oliver Kimberger' <oliver@kimberger.at>;'Reed Mike (Northumbria Health Care NHS Trust)' <mike.reed@nhs.net>
CC: 'Scott Augustine' <saugustine@augbiomed.com>;rhumble@augbiomed.com <rhumble@augbiomed.com>
Sent: 6/14/2010 11:03:14 PM
Subject: European Manuscript
Attachments: AJIC-D-10-00049[1].pdf; Manuscript_European_1.doc; response reviewer comments.doc

Guys,
Attached to this e-mail is our first draft of the European "crud and bug" manuscript based upon filtration research performed in Vienna on forced air warming devices. Just to bring you all up to speed on where we are at (particularly for those I have been out of contact with for awhile):
1) The "sister" manuscript of this research performed in the USA was recently accepted by the American Journal of Infection Control (AJIC). I have attached the manuscript to this e-mail for reference (pdf format)
2) We need to select an acceptable European journal for the European "sister" version of the US study. We would like to target an orthopedic journal with this information. So, Mike Reed, it is up to you on where you would like to see this go in. I'd target the top tier journal for we can make a good case as to the relevance of this data/research.
3) Also, I'm offering Mike the lead author role since we are targeting an orthopedic journal and Mike has also agreed to present the results at the American Academy of Orthopedic Surgeons (February).

That being said, I'd like to have all of your comments/edits by early next week. I'd like to have this submitted late next week if possible. I'm excited to see us nearing the completion point for this arm of research identifying the design deficiencies of forced air warming blowers.

Also, I'd like to extend a warm thanks to Oliver Kimberger for hosting this research at his university last summer. As such, we would like to offer you (Oliver) a spot as a co-author on the manuscript. Further, I've attached the reviewer's comments on the US manuscript to be published in AJIC for Oliver's reference.

Best Regards
-Mark

Mark Albrecht
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EXHIBIT DX10

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

Christopher Nachtsheim <nacht001@umn.edu>

abstract "crud and bug" !! Important !!

4 messages

albre116@umn.edu <albre116@umn.edu> Tue, May 25, 2010 at 3:10 PM
To: saugustine@augbiomed.com, Chris Nachtsheim <nacht001@umn.edu>
Cc: rhumble@augbiomed.com, malbrecht@augbiomed.com

Scott and Chris,
Here is a draft of 1 of 2 abstracts I'm going to submit on June 1. Here is my plan. Chris, I'm planning on making you an author on both abstracts. This is the first. In terms of statistics on this one, not very deep (or really any statistics here except a basic contingency table analysis using a binomial distribution assumption). Nevertheless, I'd like to include you. Scott, David is out on this one, but I had a chance to talk to him and he will stay an author on works he has already committed to. See forwarded e-mail (sent about same time). Ok, Scott that leaves you with a decision to make. Pick 1 of 3 options:
1) We ask mike reed to take lead on this abstract also (maybe preferred choice)
2) We ask bob gauthier to take lead on this
3) You take the lead author role (I also like this option equally to #1)

If I don't hear back from you before the submission date (june 1), I'll have to make a choice on my own. But I think I can reach you before then. Also, let me know if either of you have any edits you would like to see done.

Regards Mark

Forced Air Warming_abstract.doc
22K

Chris Nachtsheim <nacht001@umn.edu> Tue, May 25, 2010 at 4:22 PM
To: albre116@umn.edu

Mark---

OK here, Can you show me the analysis?

Chris
[Quoted text hidden]
--
Christopher J. Nachtsheim
Curtis L. Carlson Professor of Operations and Management Science
Chair, Operations and Management Science Department
3-245 Carlson School of Management
University of Minnesota
Minneapolis, MN 55455

Office: 612-624-1077
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albre116@umn.edu <albre116@umn.edu> Wed, May 26, 2010 at 12:02 AM

Reply-To: albre116@umn.edu
To: Chris Nachtsheim <nacht001@umn.edu>

Yep ill send it this afternoon
Thanks
M
[Quoted text hidden]
Sent on the Sprint® Now Network from my BlackBerry®

---

albre116@umn.edu <albre116@umn.edu> Wed, May 26, 2010 at 11:35 PM
Reply-To: albre116@umn.edu
To: Chris Nachtsheim <nacht001@umn.edu>, Robin <rhumble@augbiomed.com>

Chris
I didn't have internet last night but will this afternoon. I've got the file ready to send and will get it to you when I connect, probably about 8 am your time. Also, ill need your approval on the stats for the abstract we are submitting by tuesday at the latest (data collection is on sat and sunday). I'll send you the data and glm model output page, oh yea and the abstract draft. Maybe a phone call at that point? Let me know if you will be around tuesday morning

Thanks
Mark
Sent on the Sprint® Now Network from my BlackBerry®

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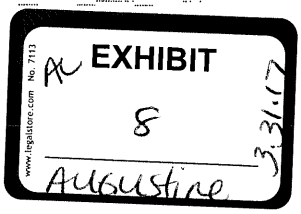
EXHIBIT DX11

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

AUGUSTINE BIOMEDICAL + DESIGN

Research Report



Document Information

Document filename:	2008-007
Creation date:	4/4/2008
Author:	Mark Albrecht

Objective:

This document presents Augustine Biomedical + Design's (ABD) research findings regarding the link between convective warming and airborne contamination. The data was obtained from two sources: 1) Prior publications in medical journals and 2) Research conducted by ABD staff in 5 hospitals within the twin cities and surrounding areas. The intent of this document is to summarize the information obtained to date and provide the rationale for further scientific investigation.

This document is structured to outline 1) the significance of airborne contamination in the Operating Theater; 2) publications assessing convective warming and airborne contamination; 3) internal ABD research activities and data; 4) promising areas for future research.

Significance of airborne contamination in the Operating Theater:

The link between airborne contamination and surgical site infection (SSI) has been well established in operating theaters[i]. Airborne contamination consists of all particulate matter suspended in the air; common forms include microbial-laden dust, lint, skin squames, and respiratory droplets[ii],[iii],[iv]. These contaminants are mobilized by air currents and can settle out of the air onto the surgical site. Settled contaminants can contribute to SSI through at least two mechanisms: pathogenic contaminants can be the direct cause of SSI; or non-pathogenic contaminants can enable SSI through the forming of a nidus for pathogen growth and attachment[v].

Of special importance is the relationship between airborne contamination and SSI for procedures involving implantable devices. Implants exhibit enhanced susceptibility to bacterial infection due to the inhibitory effects foreign materials have on the human immune system. Petty et al.[vi] demonstrated this though inserted a number of foreign materials into the femur of dogs with graded doses of bacteria. The foreign material was found to significantly reduce the

inoculum of bacteria required to initiate infection, with reduction factors ranging from 1/100th to 1/10,000th of the control dose for un-cemented cobalt chrome and methylmethacrylate cemented joints respectively. In fact, Petty et al. concluded that the presence of a single bacterium may be enough to initiate joint sepsis for some implantable materials.

The clinical relevance of these findings, in terms of the relationship between airborne contamination, implant susceptibility, and SSI, were extensively studied by Charnley from 1960 to 1970[vii],[viii],[ix]. Charnley conducted multiple center clinical trials involving nearly 10,000 orthopedic operations. The effects of airborne contamination, measured through washout counts of viable bacteria within the operational site prior to wound closure, and subsequent joint sepsis rates were evaluated. The trial was conducted in three primary environments: ORs with conventional turbulent ventilation, ORs with HEPA laminar flow ventilation, and ORs with HEPA laminar flow ventilation with staff wearing body exhaust suits. Charnley deduced that 98% of viable bacteria within the wound in ORs with conventional turbulent ventilation were due to airborne contamination settling in the wound. This was apparent because washout counts for surgeries conducted in HEPA environments with body exhaust suits were 1/98th the value of washout counts collected in the conventional turbulent environment; in both environments the surgical procedures were identical. Charnley's clinical findings are summarized in Figure 1 as percentage of cases with joint sepsis based upon treatment practice. The findings clearly demonstrate the significance of the relationship between airborne contamination and orthopedic joint infection.

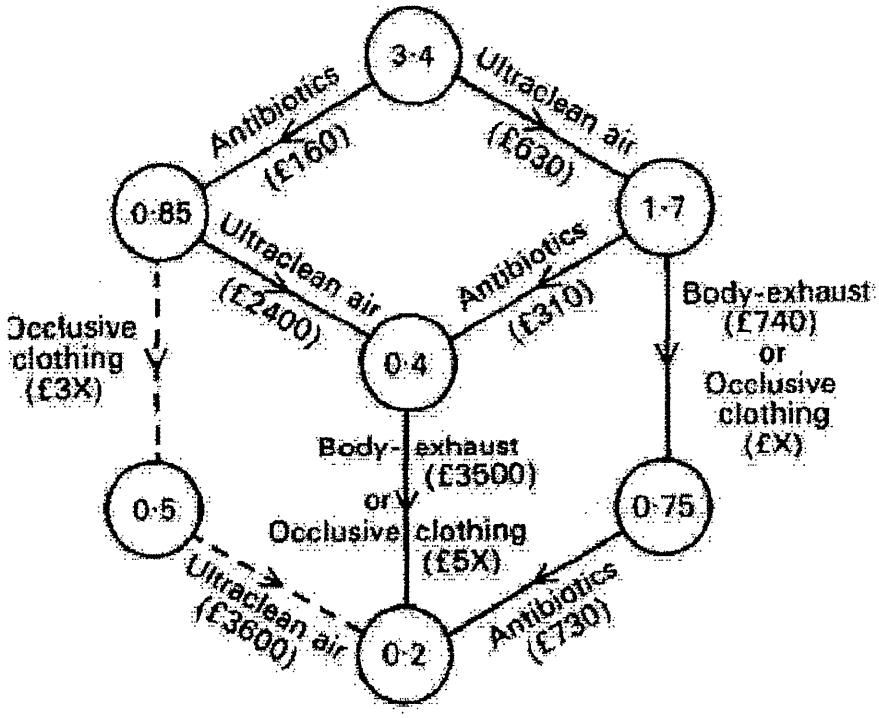


Figure 1: Joint sepsis rates for the multi center trial summarized from Charnley's research[x]. Associated treatment costs included based upon 1982 prices.

Publications assessing convective warming and airborne contamination:

To date, few research publications exist assessing the risk of airborne contamination emission from convective warming units; furthermore, the conclusions of these underpowered studies are often contradictory. The following is a complete list, at least to our knowledge, of the published research studies segmented by the publication's conclusion:

Identify Convective Warming as an Airborne Contamination Hazard:

- Avidan et al.[xi] cultured approximately 5 convective warmers by 1) swabbing the inside of the hose and 2) blowing the distal hose end air stream over agar plates. Heavy colonization was detected in the hose swabs and nearly all of the agar plates grew organisms captured from the air.
- Bernards et al.[xii] traced an outbreak of drug resistant acinetobacter baumannii to dust sampled from the inside of a convective warmer and respiratory ventilators. Cleaning the inside of the equipment stopped future outbreaks.

- Beavers et al.[xiii] researched the causes of an acinetobacter baumannii outbreak in two Kentucky hospitals. Although their research did not directly measure pathogen content of convective warmers nor identify them as a direct causative factor involved in the outbreaks, in the discussion they did identify convective warmers as a potential reservoir of infection.
- Tumia et al.[xiv] studied the effect of convective warming on airborne bacterial counts in ultra clean operating theaters. They detected a small rise in air-borne bacterial levels near the surgical site due to the use of convective warming equipment. However, the study also shows that clinician movement generated larger increases in airborne bacterial levels near the surgical site than the use of convective warming did.
- Baker et al.[xv] cultured a convective warming unit routinely used in ultra clean orthopedic theaters by swabbing the exterior and interior of the device. Heavy colonization was detected in all samples. Based upon prior research and their own data, Baker et al. make a statement recommending against the use of convective warming for orthopedic procedures based upon the elevated risk of SSI.
- In an AORN review of why hypothermia/warming protocols are not widely used, Weirich[xvi] identifies the risk of field contamination posed by forced air warming as one of the causative factors. Weirich did not collect any data and relied upon the aforementioned publications for support.
- A round table review[xvii], published in Anesthesiology News, the panel identifies forced air warming as a possible causative factor for field contamination.
- Cooke et al.[xviii] recommend hospitals undertake a risk assessment before adopting forced air warming due to the risks of pathogenic organism emission from contaminated units. Cooke et al. also identify that the research to date does not permit an assessment of cross infection risks posed by use of forced air warming devices.

Do Not Identify Convective Warming as an Airborne Contamination Hazard:

- Zink et al.[xix] performed a cross-over study on n=8 volunteers assessing bacterial counts recorded on a settling plate placed on the abdomen of the subject for two treatment conditions: 1) Convective warming blanket applied but not activated 2) Convective warming blanket applied and activated. No significant increases in bacterial counts were observed between the two treatments.

- Huang et al.[xx] assessed airborne bacterial counts for n=16 patients undergoing an abdominal vascular procedure. They did not detect an increase in airborne bacterial levels associated with the use of convective warming devices.

Based upon the research presented, it is difficult to make an accurate inference about the risks of airborne contamination emission from convective warming devices in the general hospital population of units. Publications that identify convective warming as a hazard typically base their conclusion upon direct measurements of the unit, such as internal/external surface swabs and/or organisms captured from air emitted at the distal hose end. Publications that do not identify convective warming as a hazard typically base their conclusion on indirect measurements where the convective warmer is only one of many probable contamination sources, such as particles emitted from clinician or patient skin flora; the conclusion reached in this case from indirect measurements can be interpreted as the use of convective warming equipment did not elevate airborne bacteria levels at the measurement site by a sufficient amount to be detected relative to other sources.

Given that nearly all publications identified positive swab cultures from the internal surfaces of the convective warming units, there is probable cause to believe that some level of airborne contamination is being emitted from most units. However, as the studies using indirect measures show, it is unclear as to whether the level of emitted airborne contamination is sufficient to pose a clinical risk. Furthermore, very little is known about the distribution of contamination levels in the general population of convective warming units. At present, a more comprehensive study is needed to ascertain the true airborne contamination risk posed by the use of convective warming devices that is statistically representative of the entire population. In preparation for such a study, ABD has gathered pilot data from 4 hospitals that is presented in the next section.

Internal ABD Research Activities and Data:

To date, ABD has collected primary data from 5 hospitals located in the Twin Cities and surrounding communities. All data consists of direct unit surface or air stream measurements; we did not focus on indirect unit measurements at this time because of 1) the substantially lowered detection limits and 2) the lack of published data for direct unit measurements, which

should be obtained to characterize the unit population before indirect measures are undertaken. The data gathered by ABD assessed the viable and non-viable components of airborne contamination through the following measurements:

- *Laser particle counting (viable & non-viable)*: Particle counts were recorded in the ambient operating theater, near the convective warming unit's air intake, and inside the air stream exiting the distal hose end. Reported particle counts represent the number of viable and non-viable particles of a given size range within a cubic foot of air.
- *Swabbing (viable)*: Swabs were taken of the internal hose surfaces in two locations: proximal hose end and distal hose end. Reported colony forming units represent the number of bacteria (viable particles) extracted by on each swab that survived to propagate on the Petri dish.
- *Impaction and Filter capture of airborne particles (viable)*: Impaction and filtration capture methods were applied to enumerate viable airborne contamination measured in the ambient operating theater and inside the air stream exiting the distal hose end using the following equipment; Biotest RCS plus air sampler, Andersen N-6 impactor, and a custom filter capture method. Reported colony forming units represent the number of bacteria (viable particles) captured from a unit volume of air that survived to propagate on the culture medium.

The results for each measurement technique are presented in the following sections: 1) Particle Counting Results 2) Swabbing Results 3) Airborne Impaction Results. [As a note: the sections presented below summarize the results of numerous test protocols and reports.]

Particle Counting Results:

Particle counting was applied to 1) characterize the environment that the convective warming units were sampled from 2) identify the magnitude of airborne contamination emission from convective warming equipment and 3) investigate causative factors for this emission. The data pertaining to this analysis is best presented by summarizing it into three sections: 1) Hospital ventilation particle counts 2) Distal hose end particle counts and 3) Paired intake and distal hose end particle counts.

Hospital Ventilation Particle Counts:

Figure 2 shows a combined scatter plot of the ventilation particle counts taken in all 5 hospitals grouped by sampling date; the primary intent is to illustrate the range of OR air cleanliness that

the population of convective warmers was sampled from. Particle counts were recorded near the ceiling ventilation plenum and represent the particle counts which should be expected in an OR at rest (no occupancy).

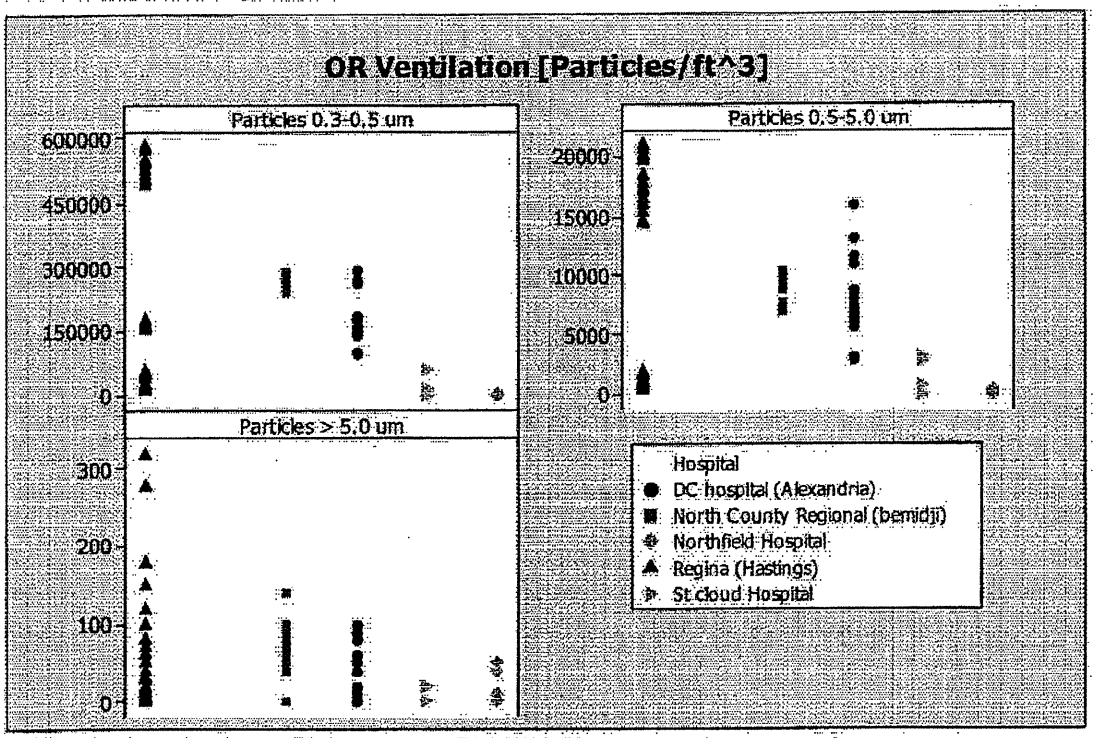


Figure 2: Combined data for OR Ventilation Particle Counts (n=111 data points)

As shown by the data in Figure 2, particle counts vary by hospital and the ventilation system employed. Hospitals such as St. Cloud and Northfield, whom employ a true HEPA ventilation system, deliver virtually particle free air to their ORs; hospitals such as DC, Regina, and North County Regional, whom employ conventional ventilation systems meeting the minimum standards[xxi], generally deliver air to their ORs that has been filtered to an efficiency of 90% relative to outdoor air.

Distal Hose End Particle Counts:

Figure 3 shows a combined scatter plot of the OR ventilation particle counts and distal hose end particle counts by hospital and sampling date; the primary intent is to show the magnitude of distal hose end particulate emission relative to ambient OR particulate levels at rest. All distal hose end particle counts are represented with a solid circle, whereas OR ventilation particle

counts are shown as open circles. The data shown in Figure 3 is too general to illustrate any trends at this moment, but we will re-visit a subset of this data once convective warming unit filtration efficiencies are analyzed.

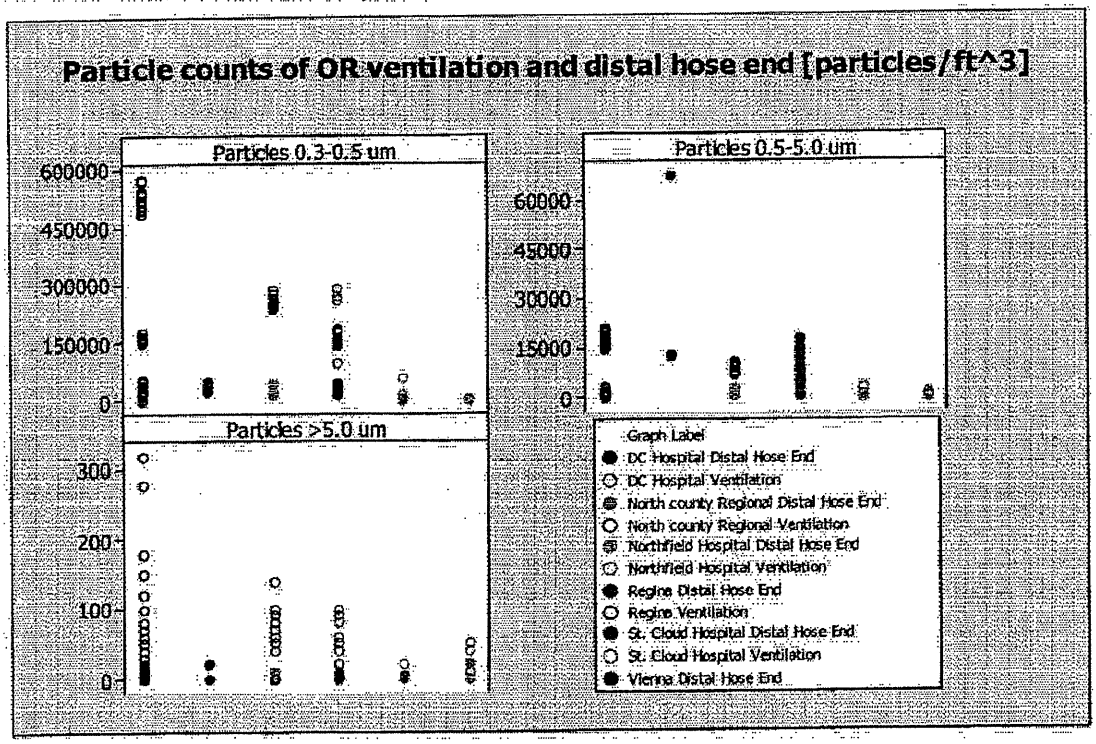


Figure 3: OR ventilation (n=111 data points) and Distal Hose End (n= 29 units, with replicates for n=76 data points) particle counts by hospital and sampling date

Paired Intake and Distal Hose End Particle Counts:

Figure 4 shows a scatter plot of paired sampling data for particle counts performed at the following two locations on the same convective warming unit grouped by hospital and sampling date: 1) Within the intake air stream prior to the intake filter and 2) Within the air stream exiting the distal hose end. All intake particle counts are represented with open circles, whereas all distal hose end counts are represented by solid circles. Figure 5 shows the calculated filtration efficiency for each paired data point taken on the same convective warming unit grouped by hospital and sampling date.

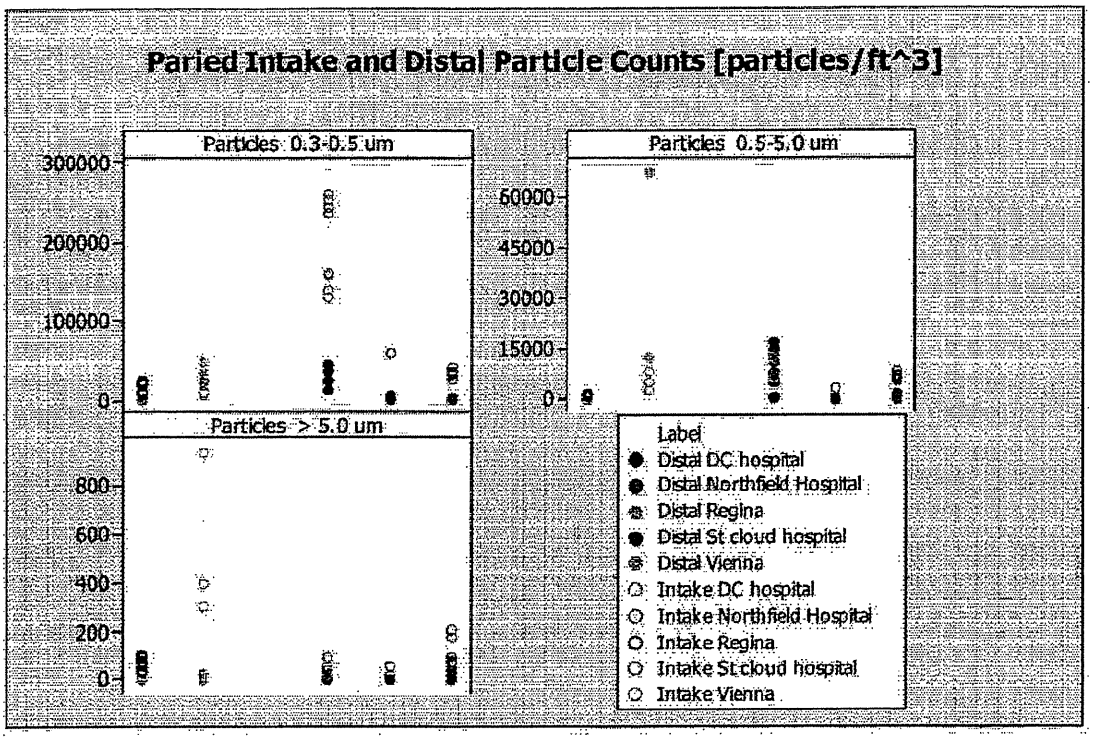


Figure 4: Paired Intake and Distal Hose End Particle Counts grouped by hospital and sampling date (n=18 units, some with replicates n=35 data points).

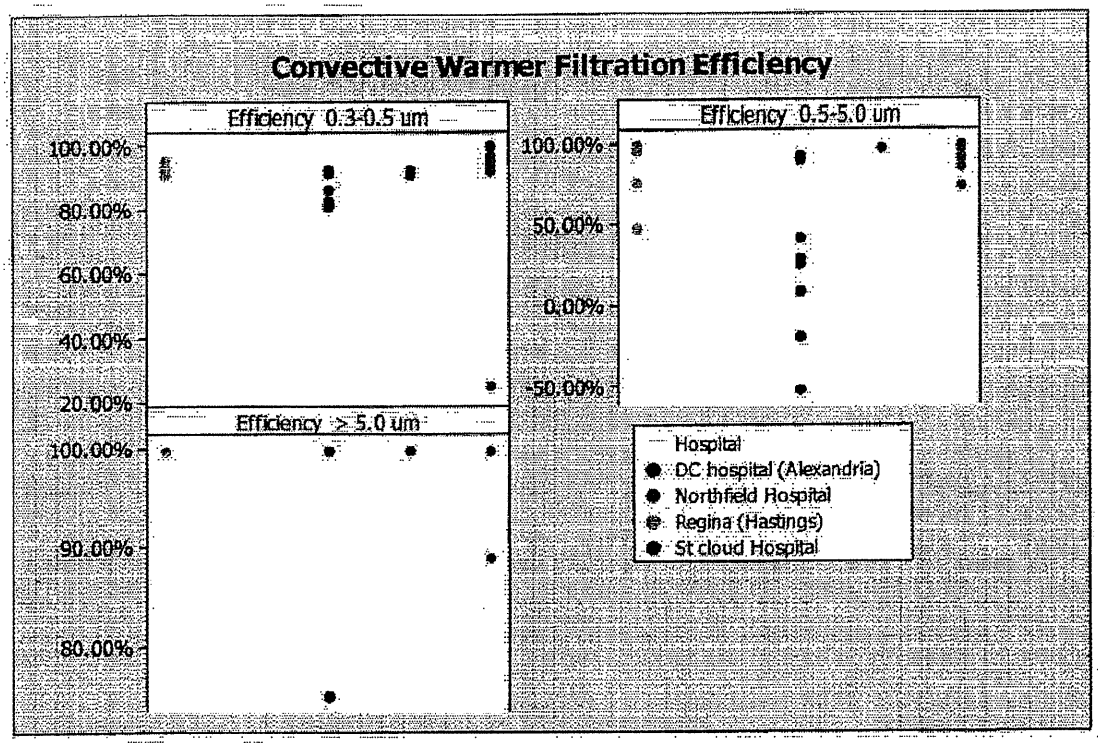


Figure 5: Calculated Filtration Efficiency for paired unit intake and distal hose end particle counts (n=15 units, some with replicates n=32 data points) (As a note: University of Vienna units omitted from data set for Y-axis scaling because they exhibited large negative filtration efficiencies, meaning the air exiting the distal hose end had higher particle concentrations than the air entering the unit. This trend is clearly displayed in Figure 4)

The trends depicted in Figures 4 and 5 are rather alarming; there appears to be a large overall variation in unit filtration efficiency from the expected value of 94%, the filtration efficiency rating for Bair Hugger 505 intake filters (@ 0.3 um). This trend suggests the possibility that some units have either 1) become contaminated and are generating particles or 2) developed air leaks that are bypassing the intake filter. As a note, we intentionally do not consider a dirty filter as a possibility because the efficiency of a depth filter traditionally increases with dirt loading. Also, a damaged filter behaves like an air leak and does not need to be addressed separately.

The likelihood of these hypotheses can be investigated by analyzing correlations among specific particle counting measures that would be present if the hypothesis were true for the following:

Hypothesis: Unit has developed air leaks that are bypassing the intake filter:

For this situation, we assume that the filter is working properly and the unit is not internally generating particles past the downstream filter. In this case, we assume that the intake air is a mixture comprised of: 1) filtered air which has passed through the filter and 2) un-filtered air which has passed through leaks around the filter. The model for calculating efficiency in this situation is shown as Equation 1:

$$\eta_{unit} = 1 - \frac{(C_{intake}) \times (\%_{filter}) \times (\eta_{filter}) + (\%_{bypass}) \times (C_{intake})}{(C_{intake})}$$

Equation 1: Equation for unit filtration efficiency assuming leaks around filter

If the hypothesis is correct, the filtration efficiency should be offset by the same amount for each particle size range because we are dealing with a mixture of filtered and dirty air (assuming the filtration efficiency is roughly equal for all particle sizes sampled). Figures 6 & 7 show a scatter plot of filtration efficiency calculated at 0.3-0.5 um, 0.5-5.0 um, and > 5.0 um for n=18 units and n=15 units (excluding Vienna data).

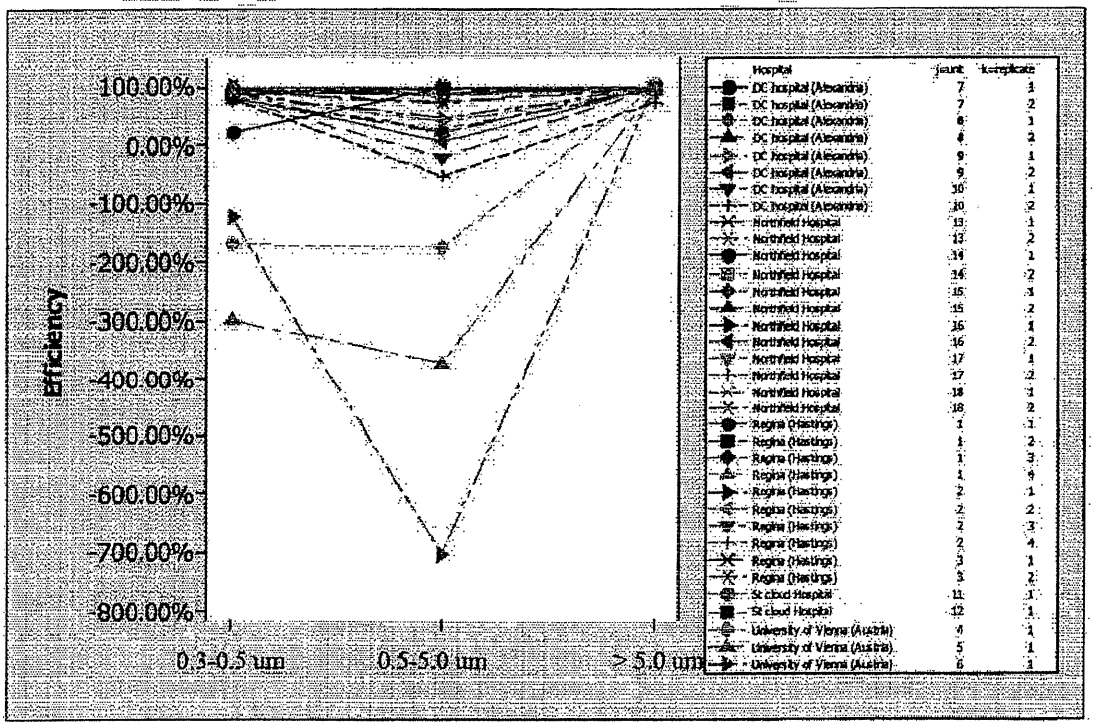


Figure 6: Filtration efficiency grouped by unit and replicate (n=18 units).

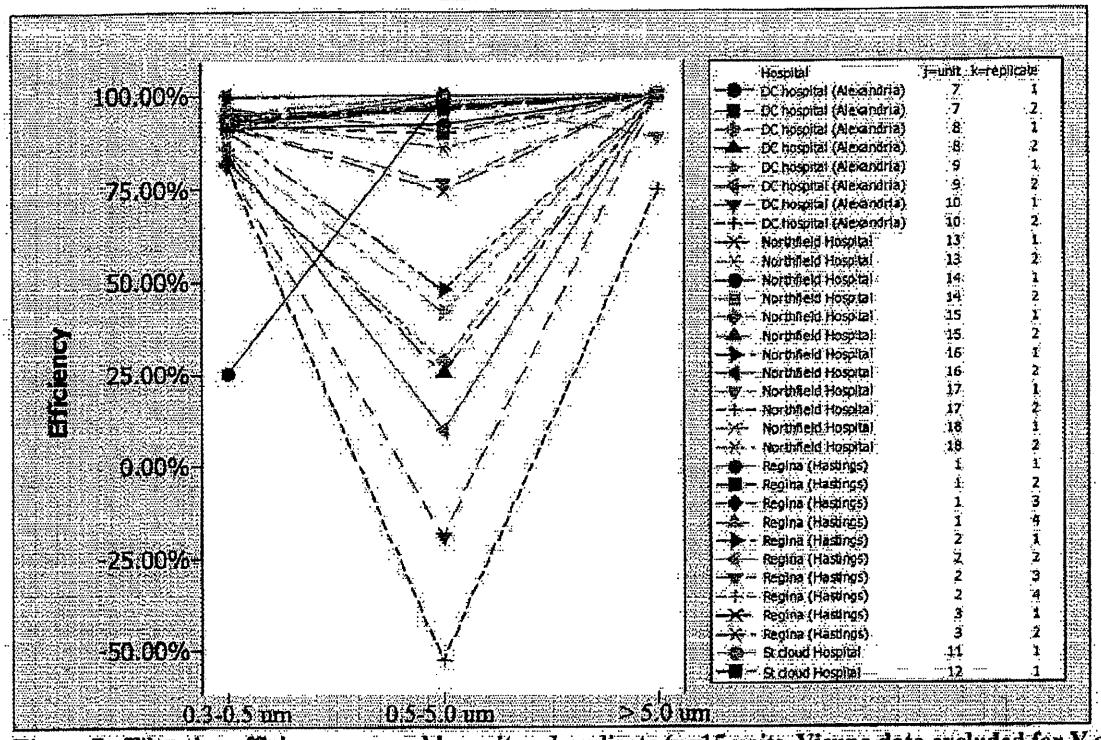


Figure 7: Filtration efficiency grouped by unit and replicate (n=15 units, Vienna data excluded for Y axis scaling).

Figures 6 & 7 display a dramatic drop in efficiency for ½ of the data points in the 0.5-5.0 um particle range. If air leaks were responsible for the observed efficiency drop shown in Figure 5 for some of the units, we would expect the 0.3-0.5 um efficiency to be equal to or lower than the efficiency at 0.5-5.0 um for these units; this result is expected because the portion of air passing through the filter and leaks will be the same for both, but the filter will operate at a higher extraction efficiency for larger less penetrating particles (0.5-5.0 um) than smaller more penetrating particles (0.3-0.5 um). As shown in Figure 6, air leakage does not appear to be the causative factor for the variation in unit filtration efficiency.

Hypothesis: Unit has become contaminated and/or is generating contamination:

This hypothesis can be tested by assuming that the filter is operating properly with minimal air leaks, but the unit is internally generating airborne contamination. The airborne contamination could be of viable (ex. colony growth) or non-viable (ex. plastic chunks) origin. Furthermore, the airborne contamination may have a specific size

distribution and only affect particle counts within certain particle size ranges. The model representing filtration efficiency in this case is shown as Equation 2.

$$\eta_{unit} = 1 - \frac{(C_{Intake}) \times (\eta_{Filter}) + (Source)}{(C_{Intake})}$$

Equation 2: Unit Filtration efficiency assuming a particle source exists

One way to confirm the contamination generation hypothesis is to identify a particle source with a size distribution that tends to impact unit filtration efficiency for a specific particle size range more so than for other size ranges; thus, ruling out the possibility that an air leak could explain the observed discrepancy in efficiency. The efficiency data in Figures 6 & 7 identify just such a source, one that appears to be generating particles within the 0.5 to 5.0 um size range for some units.

Figures 8, 9, & 10 depict the magnitude of particulate matter being generated by the source relative to what would be expected for a unit operating at a filtration efficiency of 94%. As seen by the data, there appears to be a cluster of units operating at their expected filtration efficiency of 94%, which is displayed as a black line on the graphs. However, there are also a number of units that clearly deviate from this group; these are the units suspected of generating airborne contamination. The magnitude of airborne contamination generation can be identified by calculating the X axis distance between the data point and the expected filtration efficiency line.

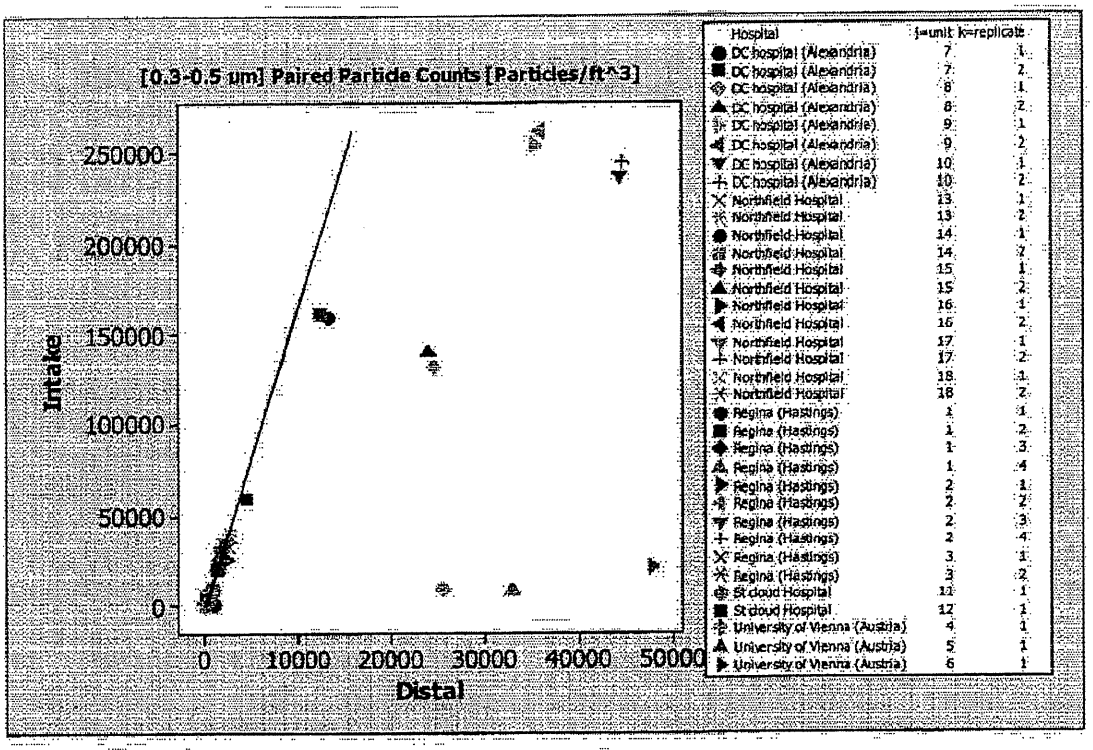


Figure 8: Paired Intake and Distal hose end particle counts for n=18 units, black line represents expected unit filtration efficiency (94%).

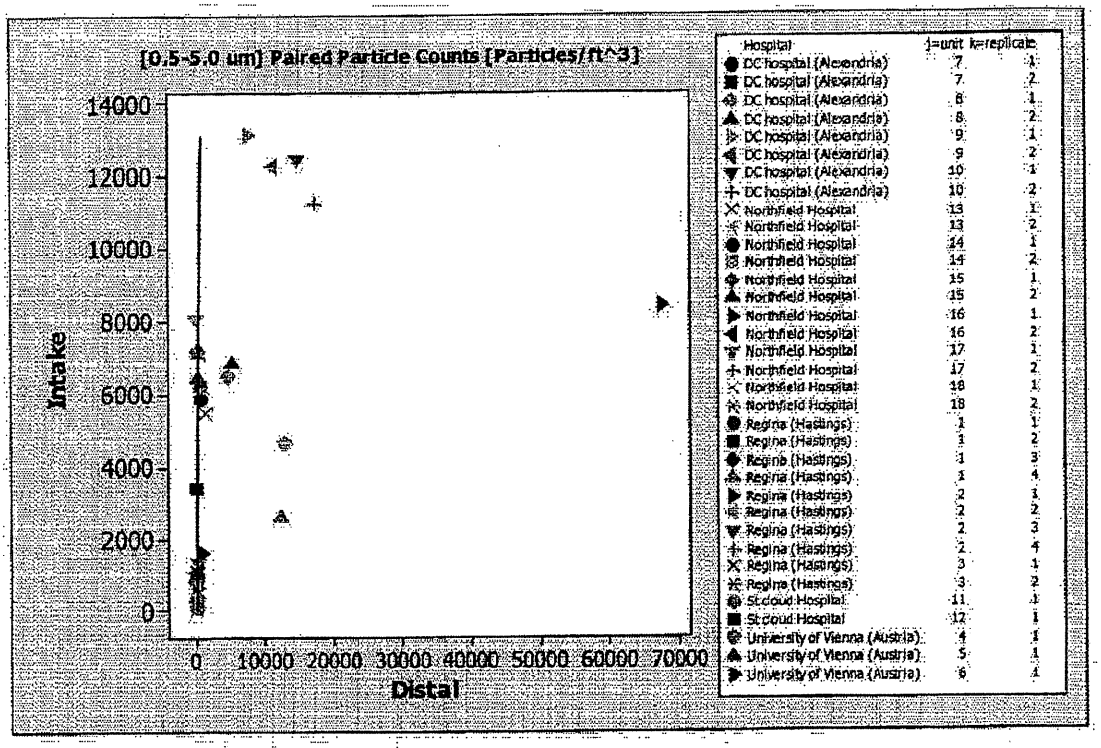


Figure 9: Paired Intake and Distal hose end particle counts for n=18 units, black line represents expected unit filtration efficiency (94%).

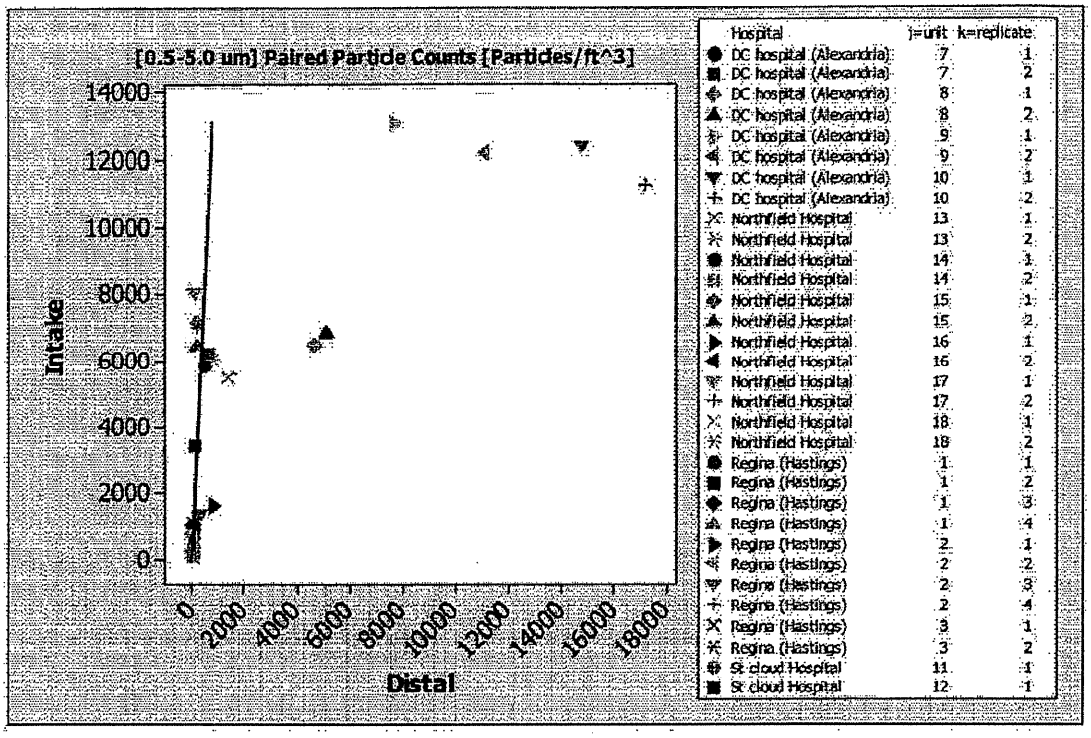


Figure 10: Paired Intake and Distal hose end particle counts for n=15 units (Vienna units excluded for X axis scaling), black line represents expected unit filtration efficiency (94%).

To quantify the degree of deviation each unit expressed from the expected filtration efficiency, a 1-way ANOVA (I) model was fitted with each unit as a factor and the response modeled as deviations from expected filtration efficiency. The model is shown as Equation 3 and the corresponding ANOVA (I) tables as Table 1 [0.3-0.5 um] and Table 2 [0.5-5.0 um].

$$Y_{ij} = (Distal\_Particle\_count) - (Intake\_Particle\_count) \times (1 - 94\%)$$

$$Y_{ij} = \mu_i + \varepsilon_{ij}$$

Equation 3: ANOVA (I) model

One-way ANOVA: Yij 0.3 0.5 versus j=unit

Source	DF	SS	MS	F	P
j=unit	17	5315910006	312700589	2530.67	0.000
Error	17	2100594	123564		
Total	34	5318010600			

S = 351.5 R-Sq = 99.96% R-Sq(adj) = 99.92%

Individual 95% CIs For Mean Based on

Level	N	Mean	StDev	Pooled StDev
1	4	59	140	*
2	4	365	310	*
3	2	112	103	*
4	1	24994	*	(*
5	1	32641	*	(*
6	1	46739	*	*)
7	2	3188	703	*
8	2	16257	813	(*
9	2	20363	148	(*
10	2	30126	205	*
11	1	85	*	*)
12	1	902	*	(*
13	2	402	299	*)
14	2	408	580	*)
15	2	-123	122	*
16	2	-175	45	*
17	2	-182	284	*
18	2	-8	2	*

0 15000 30000 45000

Pooled StDev = 352

Table 1: ANOVA (I) table for [0.3-0.5 um]

One-way ANOVA: Yij 0.5 5.0 versus j=unit

Source	DF	SS	MS	F	P
j=unit	17	4812676944	283098644	482.46	0.000
Error	17	9975185	586776		
Total	34	4822652129			

S = 766.0 R-Sq = 99.79% R-Sq(adj) = 99.59%

Level	N	Mean	StDev	Individual 95% CIs For Mean Based on Pooled StDev
1	4	-35	17	*
2	4	228	361	*)
3	2	-29	9	(*)
4	1	12423	*	(*)
5	1	12124	*	(*)
6	1	67036	*	(*
7	2	178	112	*)
8	2	4479	326	*)
9	2	8599	2483	*)
10	2	15303	1767	(*
11	1	-13	*	(*)
12	1	-105	*	(*)
13	2	778	414	*)
14	2	-7	1	(*)
15	2	-239	31	(*
16	2	-28	16	(*)
17	2	-284	88	(*
18	2	1	4	(*)

0 20000 40000 60000

Pooled StDev = 766

Table 2: ANOVA (I) table for [0.5-5.0 um]

The calculated ANOVA MSE was then used to construct P-Values for the difference of each Yij from the expected particle counts at 94% filtration efficiency. Table 3 provides the P-values for each comparison:

[0.3-0.5 um]				
Hospital	i=unit	k=replicate	Yij	P_value
Regina (Hastings)	1	1	160.8	0.327
Regina (Hastings)	1	2	146.6	0.341
Regina (Hastings)	1	3	66.8	0.424
Regina (Hastings)	1	4	-142	0.654
Regina (Hastings)	2	1	774.2	0.021
Regina (Hastings)	2	2	259.2	0.236
Regina (Hastings)	2	3	393.2	0.140
Regina (Hastings)	2	4	94.8	0.461
Regina (Hastings)	3	1	185.4	0.303
Regina (Hastings)	3	2	99.6	0.456
University of Vienna (Austria)	4	1	24993.6	0.000
University of Vienna (Austria)	5	1	32640.6	0.000
University of Vienna (Austria)	6	1	46739.2	0.000
DC hospital (Alexandria)	7	1	3685.8	0.000
DC hospital (Alexandria)	7	2	2691	0.000
DC hospital (Alexandria)	8	1	16831.6	0.000
DC hospital (Alexandria)	8	2	15682.4	0.000
DC hospital (Alexandria)	9	1	20258.4	0.000
DC hospital (Alexandria)	9	2	20467.6	0.000
DC hospital (Alexandria)	10	1	30271.2	0.000
DC hospital (Alexandria)	10	2	29981.2	0.000
St cloud Hospital	11	1	85.4	0.406
St cloud Hospital	12	1	902.2	0.010
Northfield Hospital	13	1	613.6	0.050
Northfield Hospital	13	2	190.2	0.268
Northfield Hospital	14	1	816.6	0.016
Northfield Hospital	14	2	-2	0.502
Northfield Hospital	15	1	-36	0.540
Northfield Hospital	15	2	-209	0.720
Northfield Hospital	16	1	-207.2	0.718
Northfield Hospital	16	2	-143.4	0.656
Northfield Hospital	17	1	18.4	0.479
Northfield Hospital	17	2	-383	0.854
Northfield Hospital	18	1	-7	0.508
Northfield Hospital	18	2	-9.8	0.511

[0.5-5.0 um]				
Hospital	i=unit	k=replicate	Yij	P_value
Regina (Hastings)	1	1	-59.4	0.530
Regina (Hastings)	1	2	-22.2	0.511
Regina (Hastings)	1	3	-33	0.517
Regina (Hastings)	1	4	-27	0.514
Regina (Hastings)	2	1	734.6	0.175
Regina (Hastings)	2	2	-36.8	0.519
Regina (Hastings)	2	3	237.8	0.380
Regina (Hastings)	2	4	-24.6	0.513
Regina (Hastings)	3	1	-35.4	0.518
Regina (Hastings)	3	2	-23	0.512
University of Vienna (Austria)	4	1	12422.8	0.000
University of Vienna (Austria)	5	1	12124	0.000
University of Vienna (Austria)	6	1	67036	0.000
DC hospital (Alexandria)	7	1	98.4	0.450
DC hospital (Alexandria)	7	2	256.8	0.371
DC hospital (Alexandria)	8	1	4248.8	0.000
DC hospital (Alexandria)	8	2	4709.6	0.000
DC hospital (Alexandria)	9	1	6843.4	0.000
DC hospital (Alexandria)	9	2	10354.4	0.000
DC hospital (Alexandria)	10	1	14053.6	0.000
DC hospital (Alexandria)	10	2	18552	0.000
St cloud Hospital	11	1	-12.8	0.507
St cloud Hospital	12	1	-104.6	0.554
Northfield Hospital	13	1	1071.2	0.090
Northfield Hospital	13	2	485.8	0.267
Northfield Hospital	14	1	-7.8	0.504
Northfield Hospital	14	2	-6.6	0.503
Northfield Hospital	15	1	-260.8	0.631
Northfield Hospital	15	2	-217.6	0.610
Northfield Hospital	16	1	-39	0.520
Northfield Hospital	16	2	-16.2	0.508
Northfield Hospital	17	1	-346	0.671
Northfield Hospital	17	2	-221.2	0.612
Northfield Hospital	18	1	-1.8	0.501
Northfield Hospital	18	2	3.4	0.498

Table 3: Yij and P-values for each data point using t(df=17)

The P-values for each comparison clearly identify several units that appear to be operating abnormally and generating some form of airborne contamination.

Swabbing Results:

Viables were collected via swabbing and rinsing the internal surfaces of convective warming unit hoses to 1) establish the possibility that airborne contamination emanating from the distal hose end could have a viable component and 2) to estimate the proportion of convective warming units likely to have positive cultures for the general population of units.

Table 4 shows the number of colony forming units enumerated from 1) swabbing the internal hose surfaces at the proximal and distal hose ends, with the swabbing area defined by the internal hose circumference and 2 inches of depth (about 12 in^2) and 2) rinsing the internal surfaces of the hose (n=9). As seen in Table 4, nearly all of the units exhibited some form of positive culture. In addition, distal hose end CFUs generally exceeded proximal hose end CFUs; this makes sense because the distal hose end is likely to come into contact with personnel and/or fluids. However, the CFUs recorded in the proximal hose end are concerning for the following reasons:

1. Hoses are rarely disconnected so the source of the microbes is unlikely to be from contact with personnel and/or fluids.
2. The hose surface is a dry hostile environment that is unlikely to support microbial growth, therefore the microbe source is unlikely to be a self sustaining colony that was seeded the last time the hose was disconnected.

Although we are unsure of an exact explanation for the high proportion of units with positive proximal hose end cultures, it is plausible that the microbes are originating within the unit and being carried via an airborne route to the internal hose surfaces.

Hospital	Date	Unit	Proximal CFU Swabbing	Distal CFU Swabbing	Rinse CFU
Regina	9/14/2007	505	3	6	8
Regina	9/14/2007	505	2	3	6
Regina	9/14/2007	505	2	1	7
DC	9/14/2007	505	2	11	4
DC	9/14/2007	505	6	102	6
DC	9/14/2007	505	0	9	5
St cloud	10/2/2007	505	1	300	0
St cloud	10/2/2007	505	1	300	1
St cloud	10/2/2007	505	24	0	1
Northfield	1/15/2008	505	1	3	n/a
Northfield	1/15/2008	505	0	7	n/a
Northfield	1/15/2008	505	1	2	n/a
Northfield	1/15/2008	505	1	7	n/a
Northfield	1/15/2008	505	0	32	n/a
Northfield	1/15/2008	505	2	7	n/a
Regina	1/17/2008	505	0	0	n/a
Regina	1/17/2008	505	0	2	n/a
Percent of samples with positive cultures			**71%**	**88%**	**89%**

Table 4: Colony forming units (CFU) enumerated from swabbing and rinsing.

Impaction and Filter Capture of Airborne Particles (viables):

Impaction and filtration capture methods were applied to enumerate viable airborne contamination measured in the ambient operating theater and inside the air stream exiting the distal hose end using the following equipment; 1) Biotest RCS plus air sampler[xxii], 2) Andersen N-6 impactor[xxiii], and 3) a custom filter capture method. Reported colony forming units represent the number of bacteria (viable particles) captured from a unit volume of air that survived to propagate on the culture medium. The intent of the testing was to quantify the proportion of airborne contamination, of a viable origin, emanating from the distal hose end. However, the results from all three airborne capture methods were inconclusive; all suffered from insufficient levels of detection for the viable particle sizes and concentrations sampled. The results and limits of detection for each sampling method will be presented in the following sections: 1) Biotest RCS plus 2) Andersen N-6 impactor and 3) Custom filter capture.

Biotest RCS plus results:

For the first round of testing, ABD employed the Biotest RCS plus air sampler in conjunction with a custom fitment to sample the concentration of viable airborne contamination emanating from the 1) OR ventilation and 2) Distal hose end of convective warming equipment. Testing was performed in 3 hospitals, of which n=10 ORs and n=9 convective warmers were sampled. Table 5 juxtaposes particle counts, taken on the same day, and CFUs recorded from the OR ventilation when sampled at rest (no occupancy). As a note, in some cases particle counts were taken in adjoining ORs where impaction was not performed, but the particle counts are fairly uniform and should be representative of those rooms impaction was performed in.

Regina Surgery Center

Location	Average Ventilation Particle Counts			Impaction Results	
	0.3-0.5 µm [particles/ft^3]	0.5-5.0 µm [particles/ft^3]	>0.5 µm [particles/ft^3]	Impaction Volume [L]	CFU/Volume Sampled
Operating Room 1	20,675	1,035	15	1,000	0
Operating Room 2	n/a	n/a	n/a	1,000	0
Operating Room 3	15,880	955	15	1,000	0
Operating Room 4	13,476	740	16	n/a	n/a

DC Hospital

Location	Average Ventilation Particle Counts			Impaction Results	
	0.3-0.5 µm [particles/ft^3]	0.5-5.0 µm [particles/ft^3]	>0.5 µm [particles/ft^3]	Impaction Volume [L]	CFU/Volume Sampled
Operating Room 3	155,325	7,675	25	1,000	0
Operating Room 4	n/a	n/a	n/a	1,000	0
Operating Room 5	n/a	n/a	n/a	1,000	0
Operating Room 6	126,585	5,910	70	n/a	n/a
Operating Room 7	155,120	7,140	45	1,000	0

St. Cloud Hosptial

Location	Average Ventilation Particle Counts			Impaction Results	
	0.3-0.5 µm [particles/ft^3]	0.5-5.0 µm [particles/ft^3]	>0.5 µm [particles/ft^3]	Impaction Volume [L]	CFU/Volume Sampled
Operating Room 4 (HEPA)	0	0	0	1,000	0
Operating Room 8 (HEPA)	0	0	0	n/a	n/a
Operating Room 9 (HEPA)	n/a	n/a	n/a	1,000	0
Operating Room 10 (conventional)	15,520	800	0	1,000	0
Operating Room 12 (conventional)	59,605	3,030	10	n/a	n/a

Table 5: OR ventilation RCS Plus impaction results juxtaposed with particle counts performed on the same day

As seen in Table 5, no CFUs were detected by the Biotest RCS plus for any of the OR environments when sampled at rest. Table 6 shows the CFUs recorded from the distal hose end for n=9 convective warmers juxtaposed with concurrent particle counts. Sampling was performed by fitting a custom attachment to the distal hose end; this attachment ensured that air entering both the impactor and particle counter came from only the convective warming unit. Each convective warming unit had either 3 or 2 impaction samples and 1 control sample taken in succession over a 45 minute period. For the control sample, a HEPA filter was secured to the distal hose end to remove any airborne contamination from the air stream prior to impaction and particle sampling; the purpose of the control was to ensure that handling contamination was minimal.

Regina Surgery Center, Hastings						
	Sample Start Time [sec]	Impaction Volume [L]	CFU/Volume Sampled	0.3-0.5 µm [particles/ft^3]	0.5-5.0 µm [particles/ft^3]	>5.0 µm [particles/ft^3]
CW 19808 BH 505						
Active	0	1,000	1	852	716	6
Active	1,276	625	0	332	43	0
Active	2,103	250	0	383	20	0
Control (filter in place)	n/a	1,000	0	39	20	3
CW 14503 BH 505						
Active	0	625	1	567	189	2
Active	836	250	0	413	21	0
Active	1,230	1,000	0	393	19	0
Control (filter in place)	n/e	1,000	1	0	0	0
CW 08735 BH 505						
Active	0	250	0	506	60	2
Active	540	625	0	433	29	2
Active	1,395	1,000	0	649	73	0
Control (filter in place)	n/a	1,000	0	5	0	0
DC Hospital, Alexandria						
	Sample Start Time [sec]	Impaction Volume [L]	CFU/Volume Sampled	0.3-0.5 µm [particles/ft^3]	0.5-5.0 µm [particles/ft^3]	>5.0 µm [particles/ft^3]
CW 50500A1373 BH 505						
Active	0	1,000	1	12,301	1,016	0
Active	1,341	1,000	0	17,049	656	0
Control (filter in place)	n/a	100	0	78	0	0
CW 50500A1375 BH 505						
Active	0	1,000	0	16,726	3,592	3
Active	1,341	1,000	0	15,006	2,904	1
Control (filter in place)	n/a	100	0	117	0	15
CW 50500A1376 BH 505						
Active	0	1,000	1	16,047	1,179	0
Active	1,341	1,000	0	13,353	405	0
Control (filter in place)	n/a	100	0	24	0	0
St. Cloud Hospital, St. Cloud						
	Sample Start Time [sec]	Impaction Volume [L]	CFU/Volume Sampled	0.3-0.5 µm [particles/ft^3]	0.5-5.0 µm [particles/ft^3]	>5.0 µm [particles/ft^3]
CW 50500C04194 BH 505						
Active	0	1,000	0	134	14	1
Active	1,390	1,000	0	149	10	0
Control (filter in place)	n/a	100	0	0	0	0
CW 50500D05283 BH 505						
Active	0	1,000	0	250	71	6
Active	1,390	1,000	0	209	9	0
Control (filter in place)	n/a	100	0	0	0	0
CW 50500D05282 BH 505						
Active	0	1,000	0	348	37	2
Active	1,390	1,000	0	236	7	0
Control (filter in place)	n/a	100	0	10	10	0

Table 6: Convective warming equipment RCS Plus impaction results juxtaposed with concurrent particle counts

As seen in the results, a minimal level of airborne microbial contamination was detected, all of which was recorded during the first sample; this suggests 1) the possibility of a contamination bolus being ejected upon unit startup and 2) a likelihood that emitted contamination levels may be time variant. However, based upon the low number of CFUs detected in both the OR ventilation and convective warming unit samples, it appears that we may be either outside of or on the edge of the detection limits for the RCS Biotest impactor based upon microbial concentrations and particle size. To further support this statement, research shows that the RCS Biotest impactor is suitable for capturing clumped bacteria (typical size >4.0 um) but not free bacteria[xxiv] (typical size 0.5-4.0 um) based upon a D_{50} capture rating at 7.0 um. As described prior, the particle size of interest appears to be between 0.5-5.0 um. Furthermore, 1 of the 5 CFUs detected was from a control sample, which suggests that handling contamination may be a significant factor. At this point, we concluded that the results were inconclusive and sought out a more suitable instrument, the Andersen N-6 impactor.

Andersen N-6 Impactor Results:

For the second round of sampling an Andersen N-6 Impactor was employed. The Andersen N-6 Impactor has a much smaller D_{50} capture rating of 0.65 um[xxv], meaning all particles larger than 0.65 um should be captured with reasonable efficiency on the growth medium. Table 7 juxtaposes particle counts and CFUs for the ORs and convective warming units sampled. [As a note, we intended to sample all of the ORs at rest, but OR 3 in Regina had personnel traffic pass through the room while the sampler was running.]

Regina Surgery Center					
ID	Average Particle Counts			Impaction Results	
	0.3-0.5 µm [particles/ft^3]	0.5-5.0 µm [particles/ft^3]	>0.5 µm [particles/ft^3]	Impaction Volume [L]	CFU
Distal Hose end, BH50519808	1,425	35	0	850	0
Distal Hose end, BH50508735	1,350	30	0	850	0
Distal Hose end, BH50514503	1,950	433	0	850	0
Ventilation, Operating Room 1	50,977	1,720	40	425	0
Ventilation, Operating Room 2	42,735	1,320	10	425	0
Ventilation, Operating Room 3	n/a	n/a	n/a	425	7
Ventilation, Operating Room 4	24,333	1,207	107	n/a	n/a

DC Hospital					
ID	Average Particle Counts			Impaction Results	
	0.3-0.5 µm [particles/ft^3]	0.5-5.0 µm [particles/ft^3]	>0.5 µm [particles/ft^3]	Impaction Volume [L]	CFU
Distal Hose end, 50500A1376	35,825	9,360	0	425	0
Distal Hose end, 50500A1377	44,615	16,015	5	425	0
Distal Hose end, 50500A1374	12,825	540	0	425	0
Ventilation, Operating Room 2	270,475	12,990	50	425	0
Ventilation, Operating Room 4	178,575	6,780	10	425	0
Ventilation, Operating Room 5	143,780	6,060	10	425	1

Table 7: Andersen N-6 impaction and particle counting results for OR ventilation and convective warming units.

As seen in Table 7, the results seem to be inconclusive; the only real definitive positive culture occurred in OR3, but was most likely the result of personnel movement within the room. From the data at hand, it appears that we still have not achieved a sampling method with sufficient limits of detection.

Filtration Capture Results:

For the final round of sampling, 5 types of filtration media were paneled together and sewn into the shape of a sock. The sock was then sterilized and tied to the distal hose end of the convective warming unit whereby it filtered the unit's air discharge. After sampling, the filter media was aseptically removed from the sock using a sterile scissors under an environmental hood, vortexed in a nutrient media, and plated for incubation/enumeration.

The test method was first piloted on two convective warming units before large scale testing was attempted. Table 8 shows the results of the pilot test. To identify potential handling contamination, one filter sock served as a control and was placed on the distal hose end with the unit turned off. As seen in Table 8, significant levels of viables airborne contamination were detected. However, the results could also be the product of handling contamination; the filter sock was designed with no outer covering to protect the filter from physical contact.

Sample ; Filter Substances

	Filter Sock Description		
Filter Type	Control	SN: 500J22348 USA, 1:14 min *	SN:22583, 1:50 min *
L227NW 8.0	0	17	TNTC
10µm Graded HDC	1	2	0
MBF 9.6 CFM	1	1	8
C310NW	1	3	6
L220NW 6.0	1	3	9

Table 8: CFUs for 2 convective warming units with 1 control sample. (TNTC= too numerous to count)

To expand the results of the small pilot, a new filter sock was employed with the following design elements:

- An outer covering to protect the filter from handling contamination.
- A perforated pattern cut into the filter media that allowed sections of the filter to be extracted with a tweezers instead of a scissors.
- Each sock was constructed by paneling 3 filter media types together. The three filter medias were selected based upon performance in the earlier pilot.

Table 9 shows the results using the new filter sock design to sample n=8 units in two hospitals.

Regina Surgery Center			
Unit/Sample ID	CFU by Filter Type		
	L227 NW: CFU/Sample [num]	L220 NW: CFU/Sample [num]	C310 NW: CFU/Sample [num]
First Run Unit SN: 08735	0	0	0
Second Run Unit SN: 08735	0	0	0
Control Run Unit SN: 08735	0	0	0
First Run Unit SN:14503	1	0	0
Second Run Unit SN:14503	0	0	0
Control Run Unit SN:14503	0	0	0
Northfield Hospital			
Unit/Sample ID	CFU by Filter Type		
	L227 NW: CFU/Sample [num]	L220 NW: CFU/Sample [num]	C310 NW: CFU/Sample [num]
First Run Unit SN:22551	0	0	0
Second Run Unit SN:22551	0	1	0
First Run Unit SN:37551	0	0	0
Second Run Unit SN:37551	0	0	0
Control Run Unit SN:37551	0	0	0
First Run Unit SN: 24300	0	1	0
Second Run Unit SN: 24300	0	0	0
Control Run Unit SN: 24300	0	0	0
First Run Unit SN:28371	1	0	0
Second Run Unit SN:28371	0	1	0
Control Run Unit SN:28371	0	0	0
First Run Unit SN:J22348	0	0	1
Second Run Unit SN:J22348	0	0	0
First Run Unit SN:22853	1	2	0
Second Run Unit SN:22853	0	0	0
Control Run Unit SN:22853	0	0	0

Table 9: CFUs detected for first run, second run, and control samples.

The results indicate that very few CFUs were detected; this is surprising based upon the large number of CFUs detected prior in the smaller pilot. There are two likely explanations for this discrepancy: Either 1) handling contamination was responsible for the observed counts in the

smaller pilot –or- 2) the addition of perforations significantly altered the mechanics of particle collection in the new design. Clearly the former explanation is a likely possibility, but there is reason to believe that the placement of the perforations significantly altered the collection efficiency between the old and new sock design. In the new design, the perforations were large and completely encircled the small tear out area that was eventually sampled by the lab. The proximity and quantity of perforations near the sample tear out area suggests the possibility of a localized pressure drop based upon fluid acceleration in the region. If a localized pressure drop were to be established, very little air would penetrate the tear out filter section, thus possibly explaining the discrepancy in results.

Promising Areas for Future Research:

To Be Determined.

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EXHIBIT DX12

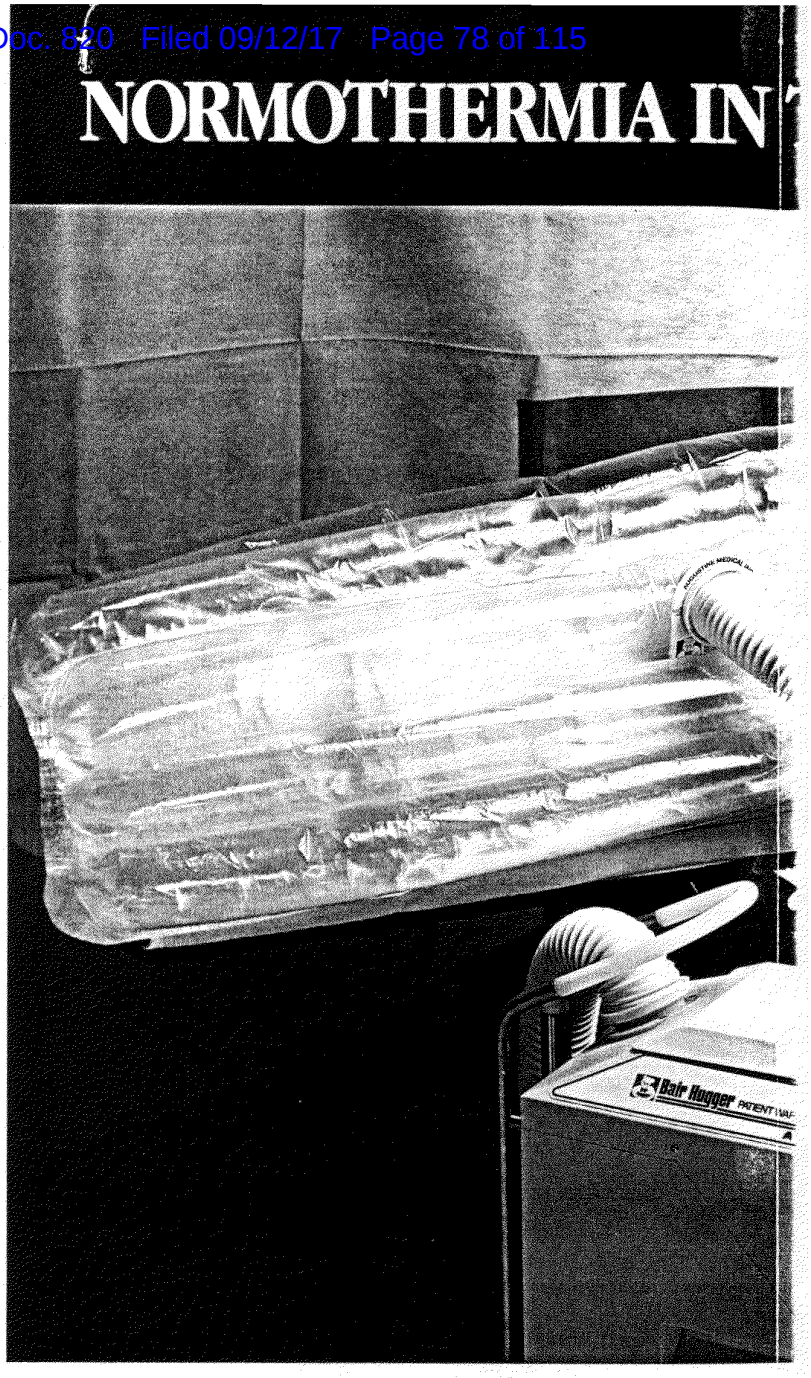
TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

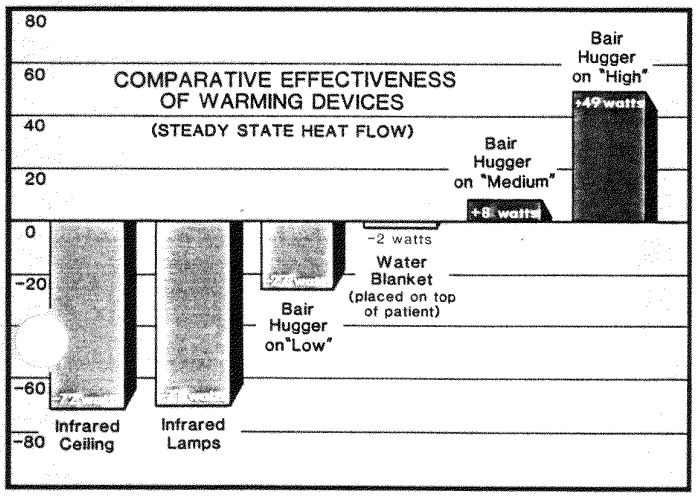
AT LAST, YOU'RE IN CONTROL!

Augustine Medical *guarantees* that Bair Hugger™ Convective Warming Therapy™ will maintain normothermia in the O.R. Far too often patients become seriously hypothermic despite the physician's best efforts. In fact, studies show that 60%-80% of all O.R. patients are hypothermic when treated with the traditional "warming" devices,[1] which are virtually ineffective.[2-4] Bair Hugger Convective Warming Therapy™ has *actively* warmed over 150,000 hypothermic PACU patients in its first year of use. It's effectiveness has been documented in several clinical studies.[2,5-8] The proven effectiveness of Bair Hugger Therapy establishes a new standard of care. With Bair Hugger Convective Warming Therapy, hypothermia in the O.R. is a problem of the past, *guaranteed!**

Bair Hugger™ Convective Warming Therapy™ is the Only Proven Method of Active Surface Warming.

Of the available methods of surface warming were tested for effectiveness at the University of California-San Francisco. Using heat flux transducers in a controlled laboratory setting, Dr. Dan Sessler found that only Bair Hugger Therapy actively transfers heat to the patient. **"...(Bair Hugger Therapy) provided enough heat to increase body temperature almost 3°C per hour."**[9] The other technologies did not transfer heat to the patient and in fact could not even prevent the patients from losing their endogenous heat.[2]





"The Bair Hugger™ is the first device that allows you to choose your patient's temperature and keep them there. We've had control of blood pressure and pulse for years, now we can finally control temperature."
Neil Feinglass, M.D., Jacksonville, FL

"Bair Hugger™ Pr Body Heat"
– American Soc Anesthesiolog Annual Mtg., N

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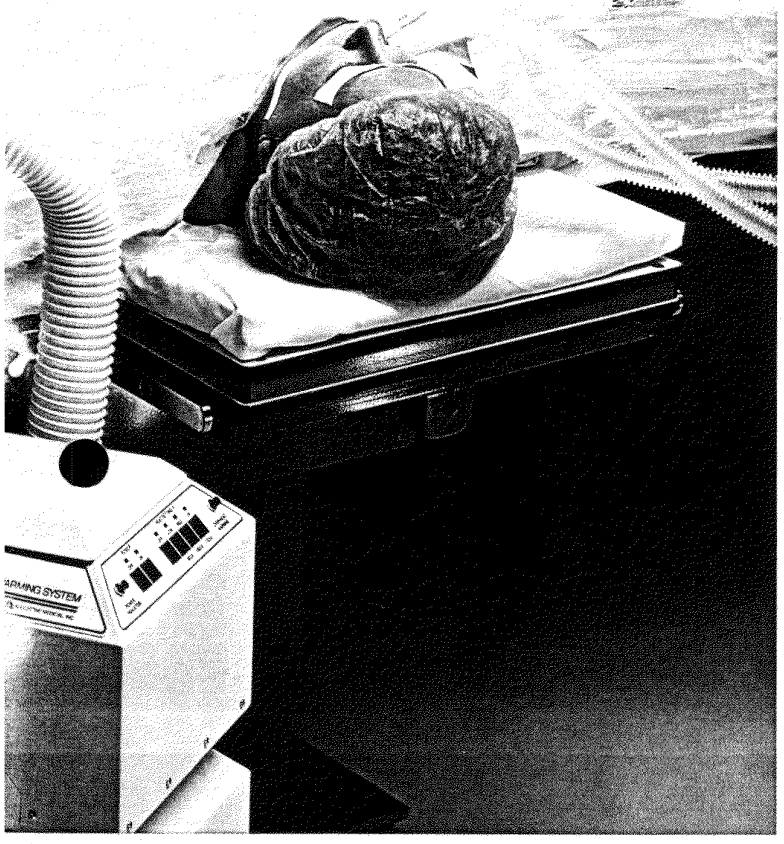
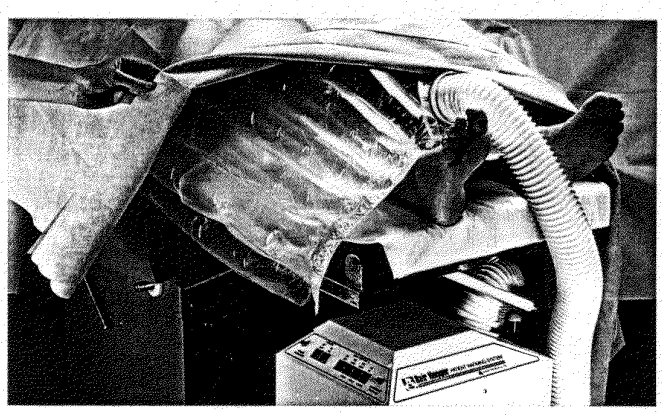




Bair Hugger™ Warming Covers are Available in Two Styles

A chest/arm Cover for abdominal and lower extremity operations and a leg Cover for abdominal, thoracic and intracranial operations.

Localized Air Flow

The combination of the Steridrape™ (3M, St. Paul, MN) barrier design and the overlaying surgical drape, prevents the warm exhaust air from migrating toward the surgical incision. The heated air flows from under the surgical drape toward the floor. It is then carried directly toward the room exhaust vents by the large volume of room ventilation air which is blowing directly down on the patient from the ceiling.

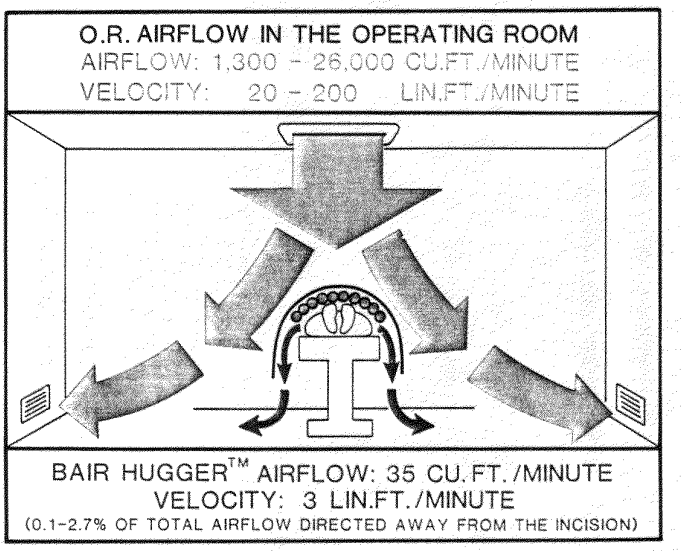
The warm air contributes less than 3% of the total air circulation in the O.R. and is undetectable at the surgical site. Bair Hugger air is filtered through a 0.2 micron filter before heating.

:evente Loss of

ciety of
gists press release,
New Orleans, LA, 1989

"The injured patient arrived in the O.R. cold and bradycardic. Active warming with the Bair Hugger™ resulted in a rapid improvement of the temperature and stabilization of the heart rate."

–K.G. Belani, M.D., Minneapolis, MN

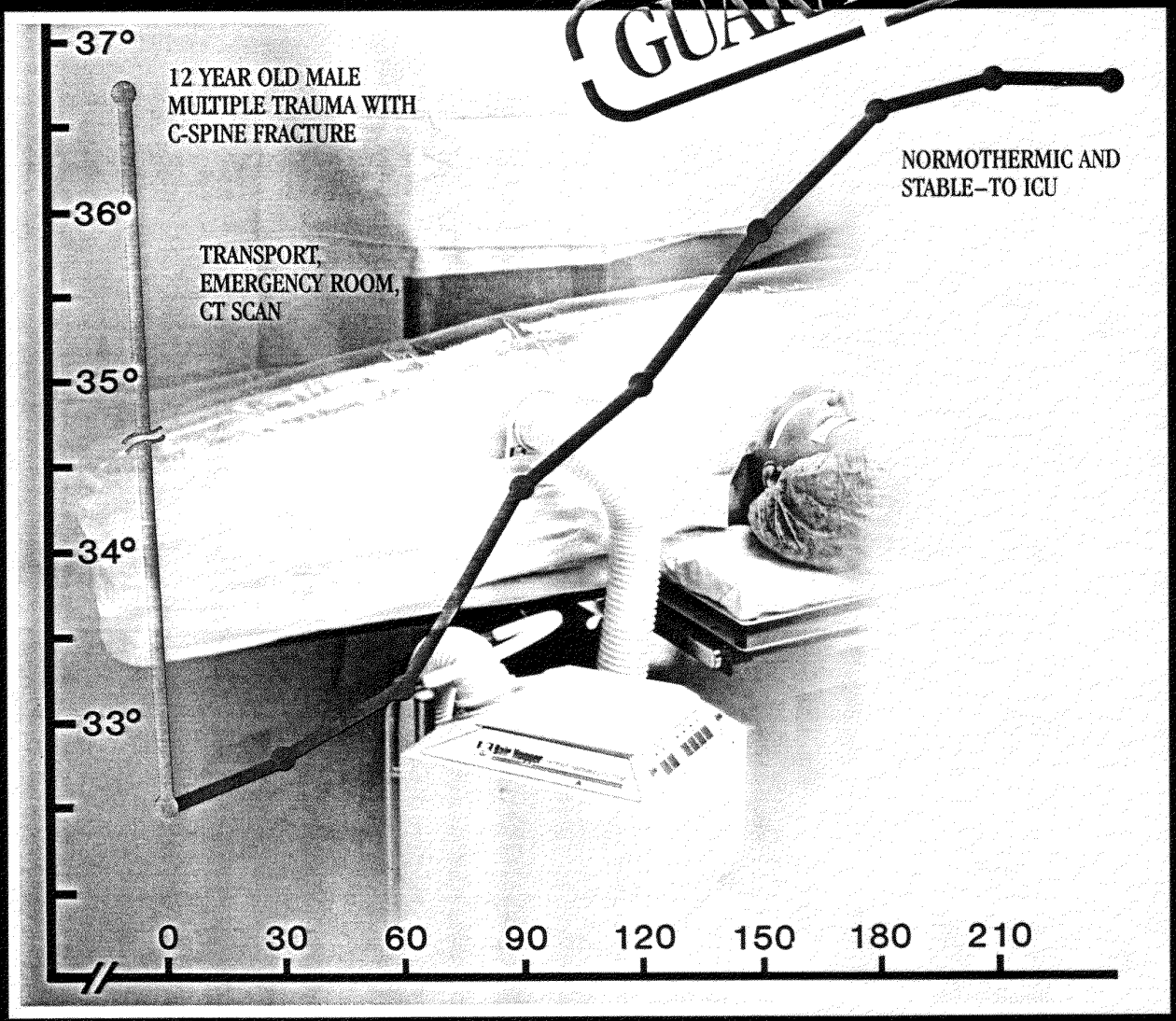


CONVECTIVE WARMING THERAPY™

AUGUSTINE MEDICAL INTRODUCES...

NORMOTHERMIA IN THE O.R.

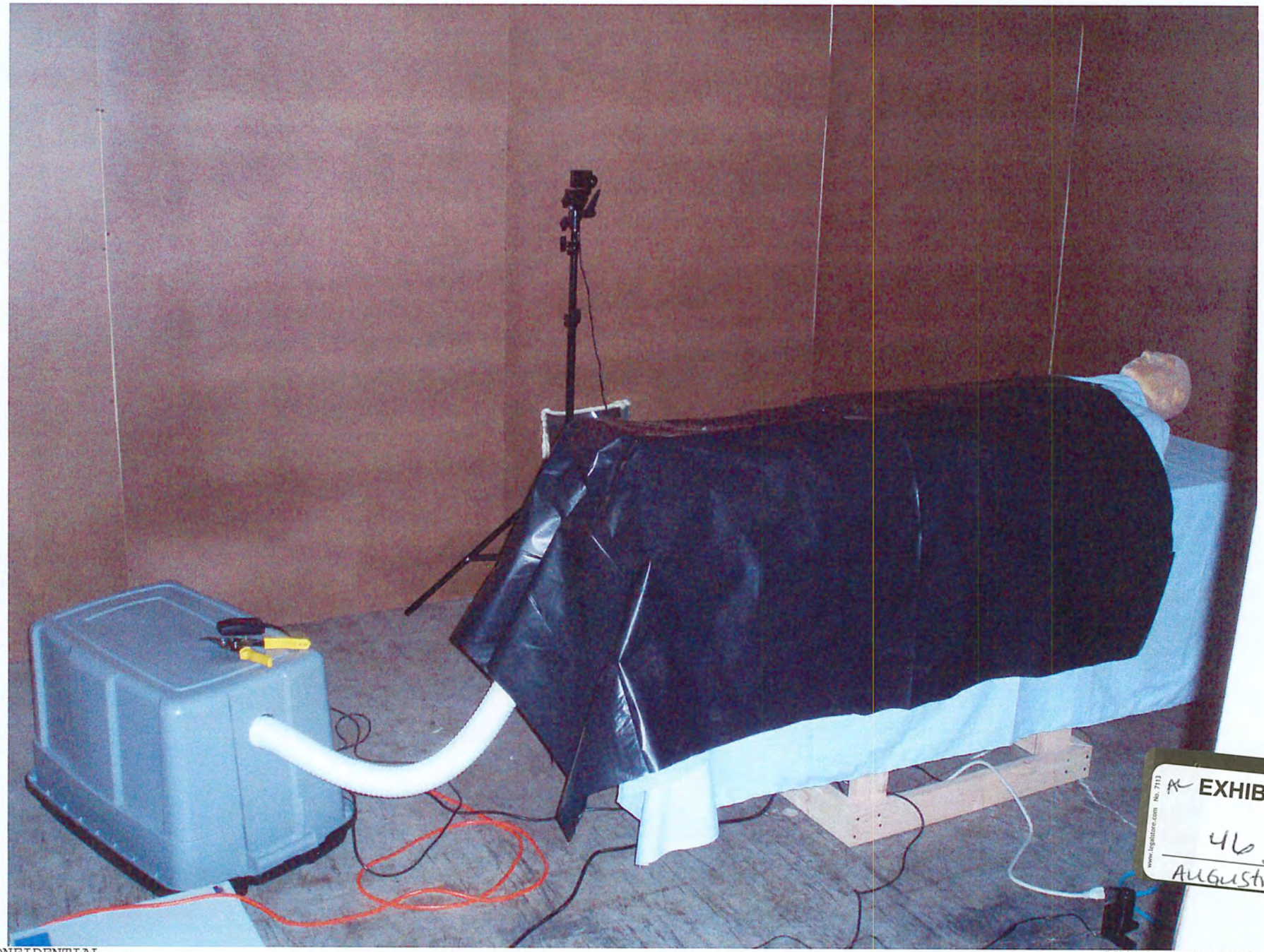
GUARANTEED*



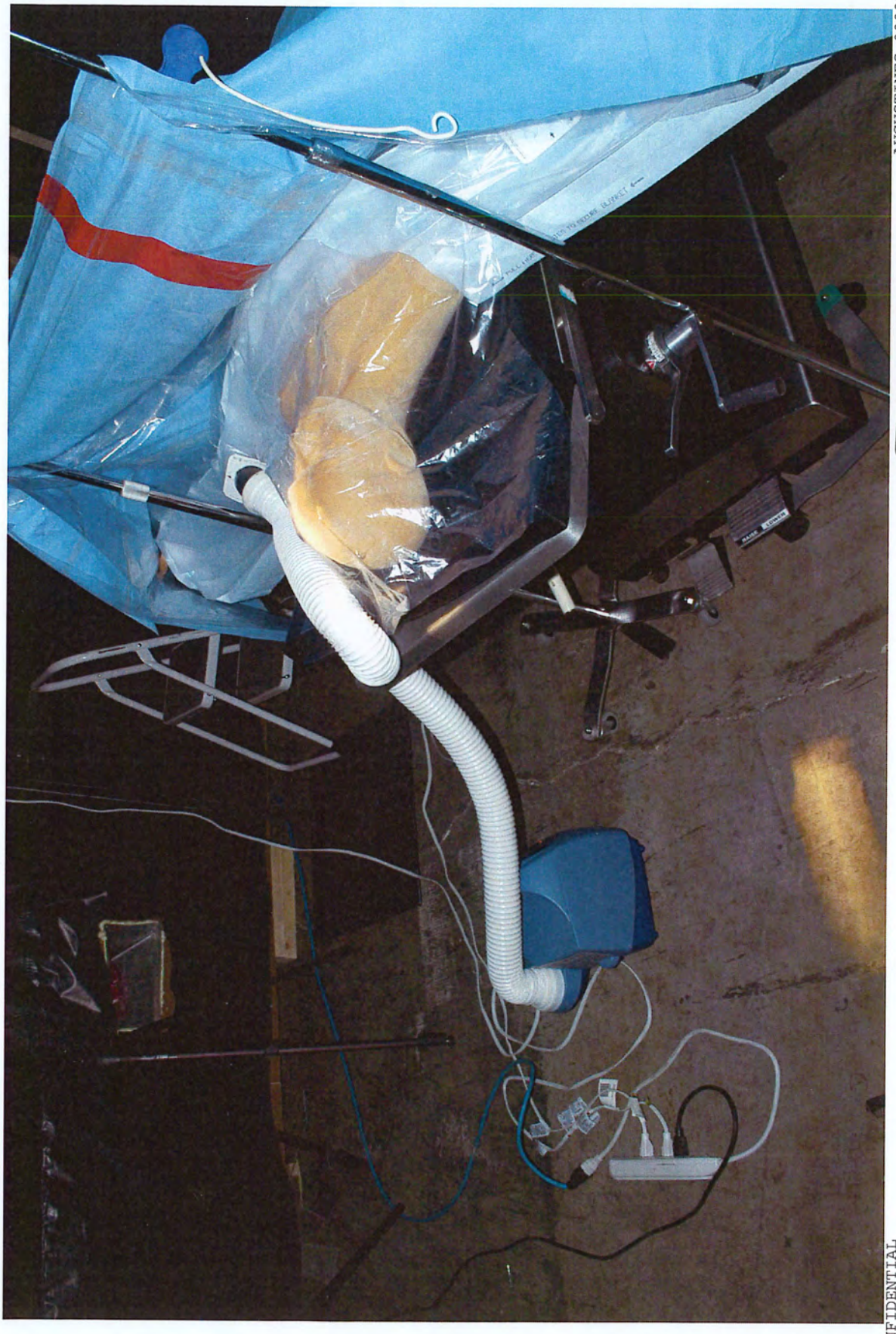
BAIR HUGGER™
CONVECTIVE WARMING
THERAPY™ STARTED IN O.R.

EXHIBIT DX13

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS




Bair Hugger
EXHIBIT
47
Augustine
3/31/17



AUGUSTINES_0000222

EXHIBIT 49 Augustine 3.31.17

CONFIDENTIAL

EXHIBIT DX14

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

October 5, 2009

Kumar Belani MD
4916 Ridge Road
Edina, MN 55436

Hi Kumar,

It's been awhile – I hope all is well with you.

I am happy to report that we are making significant progress toward making Hot Dog® warming a success. The most exciting news is that we "discovered" that heat rises! More specifically, we found that the waste exhaust heat from forced air warming (FAW), eg. Bair Hugger®, rises into the sterile operating field and totally disrupts even the most effective laminar flow ventilation.

The enclosed 4 minute DVD graphically tells the story. While you watch it, remember that there should NEVER be rising air in an operating room laminar flow field--not even at knee level, much less above the surgical site! While this is obviously not a peer-reviewed publication, it is easy to corroborate with a thermometer.

Preliminary feedback from surgeons who have seen this video, indicates that this may be the "fatal flaw" that could make forced air warming obsolete. If laminar flow disruption causes forced air warming to be removed from 1 operating room or 100,000 operating rooms, we are confident that Hot Dog [air free] warming will be the most likely beneficiary. Hot Dog warming is the only safe, effective and practical alternative at this date.

On a personal note, as the inventor of FAW, I am extremely proud of the contribution that it has made to improving patient outcomes. However, in light of the increasing risk, severity, antibiotic resistance and cost of surgical site infections (SSI), the world has changed. As a result, many operating room traditions must be re-evaluated. Considering the many recent published reports of FAW blower contamination-- and now the discovery that FAW exhaust heat disrupts laminar flow, I have come to the conclusion that FAW is a 20 year-old technology in need of retirement. I would be interested in your thoughts.

You won't be surprised to learn that I've been working on something to solve the problem. Fortunately, the new electrically conductive fabrics make air-free patient warming possible. My team has developed Hot Dog® patient warming, a safe, effective and very inexpensive air-free alternative to FAW. We continue to be confident that the Hot Dog product is at the "right place at the right time."

Finally, I want to mention that the broker for our unit (stock) offering has not yet sold his entire allocation. If you are intrigued by the apparent vulnerability of forced air warming caused by the laminar flow disruption and the huge opportunity that it creates for Hot Dog warming, I would love to talk to you about the investment opportunity. We are still accepting "friends and family" investments for the same price as offered a few months ago.

Please contact Sean Lawler, our CFO, at 952-465-3529 (slawler@augbiomed.com) or me at 952-465-3502 (saugustine@augbiomed.com) if you have questions about investing.

Warmest regards,

Scott Augustine MD
CEO
Hot Dog International, LLC

October 2, 2009

Daniel Sessler MD
Dept of Outcomes Research
Cleveland Clinic
9500 Euclid Ave/P-77
Cleveland, OH 44195

Hi Dan,
It has been awhile since we last spoke, I hope all is well with you.

Because you are a long time colleague, researcher and thought-leader in thermal regulation, I want to give you a preview of some new information that is about to be released regarding forced air warming (FAW). This is obviously not a peer-reviewed publication, however, it is easy to corroborate with a thermometer. I do believe that this information is going to cause a bit of discussion across the drapes. This may also cause a problem with FAW being the only warming technology recognized by Medicare.

The DVD is only 4 minutes. While you watch it, please remember that there should NEVER be rising air in a operating room laminar flow field - not even at knee level much less above the surgical site!

On a personal note, as the inventor of FAW, I am extremely proud of the contribution that it has made in improving patient outcomes. However, in light of the increasing risks, increasing severity, antibiotic resistance and costs of surgical site infections (SSI), the world has changed and as a result many operating room traditions must be re-evaluated. Considering the many recent published reports of FAW blower contamination and now the discovery of laminar flow disruption by FAW exhaust heat, I have come to the conclusion that FAW is a 20 year-old technology in need of retirement. I would be interested in your thoughts.

I am looking forward to seeing you at your ASA Refresher Course. I hope that we can find some free time to catch up.

Warmest regards,

Scott Augustine MD

EXHIBIT DX15

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

MICHAEL R. REED

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

- -

In re Bair Hugger Forced
Air Warming Products
Liability Litigation,

MDL No. 14-2666 (JNE/FLN)

- -

- -

VIDEOTAPED DEPOSITION OF

MICHAEL R. REED

- -

London, United Kingdom

Taken December 4th, 2016 By Rose Kay

Job No. 115951

MICHAEL R. REED

Q. Okay.

How did you come to be interested in that subject?

A. Okay. So I have been trying to recollect the exact order of events; but I am pretty sure I saw a video, which I am sure will be used in some of the evidence, which was smoke coming out of the bottom of a draped theater which was being shown around by Augustine, and I think that was in 2009, perhaps at one of the orthopaedic meetings.

I then heard David Leaper, who I think is another one of your witnesses, speaking at a conference in 2009. And following that, I contacted him by e-mail, actually, and we had an e-mail discussion about his anxiety about the fact that laminar flow was potentially disrupted by forced air.

And then --

THE EXAMINER: Was that the topic of his talk that you heard?

A. I did make some notes on it. I am actually not sure it was. There must have been something in it, in all honesty, because I did e-mail him and the conversation went that way. I have got that e-mail. But there must have been something in his talk that set me off with that discussion.

MICHAEL R. REED

And so -- and he at that point, I think, was a consultant for Augustine.

BY MR. GORDON:

Q. Are you talking about Professor David Leaper?

A. Yes. And in late 2009, we did an experiment in our theater, which was comparing forced air warming with conductive fabric warming, which was the Augustine product.

Q. Also known as the Hot Dog?

A. The Hot Dog. And that involved getting a -- essentially sucking air in, onto culture plates, to see whether there was an increased bacteria load in the theater.

And we did that with a microbiologist. There was a minor celebrity microbiologist who was a bit of a TV personality at that time who came up and did that with us, and they went off and cultured the air, if you like, that sucked onto these plates.

Q. What --

A. So --

Q. What were the results of that?

A. So what that showed was that there was no difference in contamination, whether you use forced air warming or not.

Q. Who financed that study?

MICHAEL R. REED

A. So that was financed by Augustine. He gave our department £5,000 for that.

Q. How did you connect with Dr. Augustine for that financing? In other words, did he come to you, did you go to him? Was there some other ...?

A. Yes, I am not even sure I had met him, but it was through David Leaper. David Leaper essentially arranged that. But I know the money was coming from Augustine. I don't think I had met him at that point.

Q. Okay.

So Professor Leaper arranged for funding from Augustine for you to do a microbiological study?

A. Yes. And David Leaper came as well and we did it on a weekend in theater.

Q. I have to ask. How does a microbiologist become a TV celebrity?

A. So my recollection is, it was something about the sort of -- where bacteria grow and everything. She wasn't a celebrity for that long actually, but she was a slightly colorful character and she was good for TV, I think.

Q. Was this done at one specific hospital?

A. Yes.

Q. Which one?

MICHAEL R. REED

A. Wansbeck.

Q. Okay. Is Wansbeck your primary hospital or was it back then?

A. Yes.

Q. Is it still today?

A. It is much more gray now, but it's where my office is. But I am not sure I operate any more there than I do anywhere else.

Q. Back in that 2009 timeframe, that would have been where you did more surgeries?

A. Yes.

Q. Did -- at that time period in 2009, did Northumbria Hospital Trust have its own microbiology staff?

A. Yes.

Q. Did you involve any of them in this project?

A. No. I think they probably wouldn't have been too keen because, you know, these things involve costs and hassle for the lab techs. So they are not too keen on doing ad hoc experiments like that in the microbiology department.

Q. So the people involved in this were you, Professor Leaper, this -- the celebrity microbiologist; and anyone else?

A. Yes. There would be one or two trainees, of which

MICHAEL R. REED

"During the last two quarters of 2008/2009, Northumbria Healthcare NHS Foundation Trust was reporting SSI rates in the combined total of surgeries in the THR/TKR and repair neck of femur between 3.5 percent and 5.7 percent and was regularly receiving letters from the HPA informing the trust of its high outlier status for SSI."

First of all, did I read that correctly?

A. Yes.

MR. ASSAAD: Objection. Move to strike for hearsay.

BY MR. GORDON:

Q. Did --

THE EXAMINER: (Overspeaking.) ... moving on to a question --

MR. ASSAAD: He can't read evidence in, without establishing a foundation. I am saying this is hearsay. He is reading someone else's words into the record. He is basically advocating this point. Objection for hearsay.

BY MR. GORDON:

Q. Do you recall there being a period of time when the Northumbria Healthcare Trust was getting letters from the HPA about SSI rates?

A. Yes.

Q. And what were those -- first of all, what is the HPA?

MICHAEL R. REED

A. So the HPA is the Health Protection Agency and they are the group that collate the national database, based on people collecting it locally. So Gail Lowdon who leads our surgical site infection surveillance team, a member of her team will be uploading that information nationally, if you like, to the Health Protection Agency.

The issue with that is that not every trust puts in the data as we have established; and the infection rates that they quote are very low and, in fact, they have -- I mean, the government advisers on infection have publicly written to say that their quotes -- they quote very low infection rates, unrealistically low, because the surveillance system is poor in many trusts?

THE EXAMINER: Do you have a recollection of these letters being received?

A. Yes.

THE EXAMINER: Okay.

BY MR. GORDON:

Q. And what did Northumbria do in response to those letters?

A. So I mean, we have done lots of things, as I think has become clear. We have made loads of changes over a period, a sustained period, to try and reduce the

MICHAEL R. REED

infection rates.

Q. Was there any type of a committee or a working group formed?

A. Yes. So there was a surgical site infection prevention committee, which I chair.

Q. And when was that formed?

A. It may actually even be on here. About 2008, maybe even 2007. That sort of timescale.

Q. And that's your independent recollection?

A. Yes.

Q. So the reason I say that is that on page 548, it says that the multiple -- a multi-disciplinary team formed the trust SSI group and the first meeting took place in December 2008.

A. There you go then.

Q. Well, if you --

THE EXAMINER: What is the --

BY MR. GORDON:

Q. If your recollection is different than what is here --

A. Yes, I think that feels right and she would know. What I would say is that we may have been doing stuff before that, before we did a formal meeting, but it would not have been long before that.

Q. And there is a reference in the next paragraph to:

MICHAEL R. REED

"The first action point of this meeting was to place a successful bid to appoint two full-time SSI nurses on a 12-month secondment."

MR. ASSAAD: Objection, hearsay.

BY MR. GORDON:

Q. And my question is: was there -- were there full-time SSI nurses prior to whenever this multi-disciplinary group first met?

A. Yes, so the -- the surveillance was done -- I mean, we should probably go back one step.

So we were named in the paper, based on the 2007 data, as having a high infection rate. And after that, we went to full-time surveillance, some time probably in early 2008, but we didn't have the business case and people -- and people formally appointed to those rules. They were being done, I think, by infection control, rather than by a surveillance team. Same methodology.

MR. ASSAAD: I am going to object again to those line of questions. It is not part of the subject matter of the sealed order. It has nothing to do with the studies that he has been performing, that it has been limited to -- by the Senior Master.

THE EXAMINER: He is still in the --

MR. ASSAAD: I mean, we -- well, it really isn't. It is

EXHIBIT DX16

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

FAEGRE BAKER DANIELS

CLAIM NO: CR 2016-520

IN THE HIGH COURT OF JUSTICE

QUEENS BENCH DIVISION

IN THE MATTER OF
THE EVIDENCE (PROCEEDINGS IN OTHER JURISDICTIONS) ACT 1975

AND

IN THE MATTER OF CPR PART 34

AND

IN THE MATTER OF A CIVIL MATTER NOW PROCEEDINGS BEFORE THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA ENTITLED AS FOLLOWS:

IN RE: BAIR HUGGER FORCED AIR WARMING PRODUCTS LIABILITY LITIGATION

MDL NO. 15-2666(JNE/FLN)

Plaintiffs

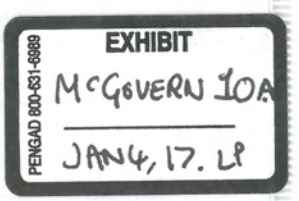
-v-

3M COMPANY AND ARIZANT HEALTHCARE INC.

Defendants

DOCUMENTS PROVIDED BY DR PAUL MCGOVERN VOLUME 8

PAGES 3539 - 3717



DO FORCED AIR WARMING DEVICES INCREASE BACTERIAL CONTAMINATION OF OPERATIVE FIELD? – Simulated experiment analysis

McGovern PD, Srinivas S, Sutaria P, Bull D, Edwards-Jones V, Reed MR

Objective: To analyse if a forced air warming device could increase bacterial contamination of the operative field.

Background: Forced Air warming units have been shown to be effective in helping to maintain intraoperative normothermia but concerns have been raised that they may blow contaminants into the operative field, possibly increasing the risk of postoperative infection.

Study design: Controlled experiments in simulated environment

Methods: A series of simulated operations were set up sequentially over one day in a laminar flow operating theatre, with airborne particle and bacterial sampling performed during the experimental period.

Results: The experiments showed no notable increase in either ambient particle count or bacterial count in the vicinity of an operative field when a forced air warming device was used in the normal intra-operative manner. There was increase in local particle counts only when the surgeon enters the operative field, from outside the laminar flow boundary.

Conclusions: Use of forced air warming devices does not increase the bacterial count in the vicinity of the operative field. However it is noted that introduction of airborne particles from outside the laminar flow zone to the operative field increases the bacterial count, many of these which could be pathogens themselves, or sterile particles that form a nidus for pathogen growth. [5]

INTRODUCTION:

The maintenance of intraoperative normothermia is an important factor in reducing the risk of perioperative complications. [1] [2] In addition to using warmed fluids for infusion and keeping the operating theatre temperature at an appropriate level, various methods exist for insulating or actively warming the patient externally.

Forced Air warming units have been shown to be effective in helping to maintain intraoperative normothermia. [3] However concerns have been raised that these devices may blow contaminants into the operative field, possibly increasing the risk of postoperative infection. [4]

There have been video demonstrations that have illustrated the convection currents that are produced during the use of forced air warming blanket. It is possible that despite laminar flow, the currents which are produced appear to flow in a direction that could contaminate an operative site. *(reference?)*

The purpose of this study is to investigate the effects during the use of a forced air warming unit particularly on the bacterial count in the vicinity of the operative field. The investigations were carried out in a simulated environment and we present our findings from these experiments and discuss the possible implications to surgical practice.

METHODS

A series of simulated operations (referred to as 'experiments') were set up sequentially over one day in a laminar flow operating theatre. One of the authors acted as a patient, and was prepared and draped for surgery, with a Bair Hugger blanket in position but turned off initially. Airborne particle and bacterial sampling was performed at different times during the experimental period, over periods when the bair hugger unit was off and then switched on.

An active laminar flow operating theatre was used for the purposes of this experiment. The investigating team consisted of 4 members – a surgical trainee, two Foundation Year 2 doctors and a professor of microbiology. A real-time operative environment was simulated. All members wore standard theatre scrubs, surgical caps and face masks. Entry and exit of personnel was minimised, and only permitted through the scrub room door.

Four different experiments were performed and each had variations to the sampling protocol as described below.

Airborne particles were counted throughout each experiment using a handheld particle counter *[Handilaz mini® Particle Measuring Systems Inc. Boulder USA]*. This samples air at a constant rate and draws it through a laser array, measuring light diffraction and inferring a particle count.

Bacterial samples were taken using settle plates. (5% (v/v) Columbia Blood Agar (CBA), MRSA select, Sabauraud agar, Cysteine lactose electrolyte deficient (CLED) and *Clostridium difficile* agar) were used.

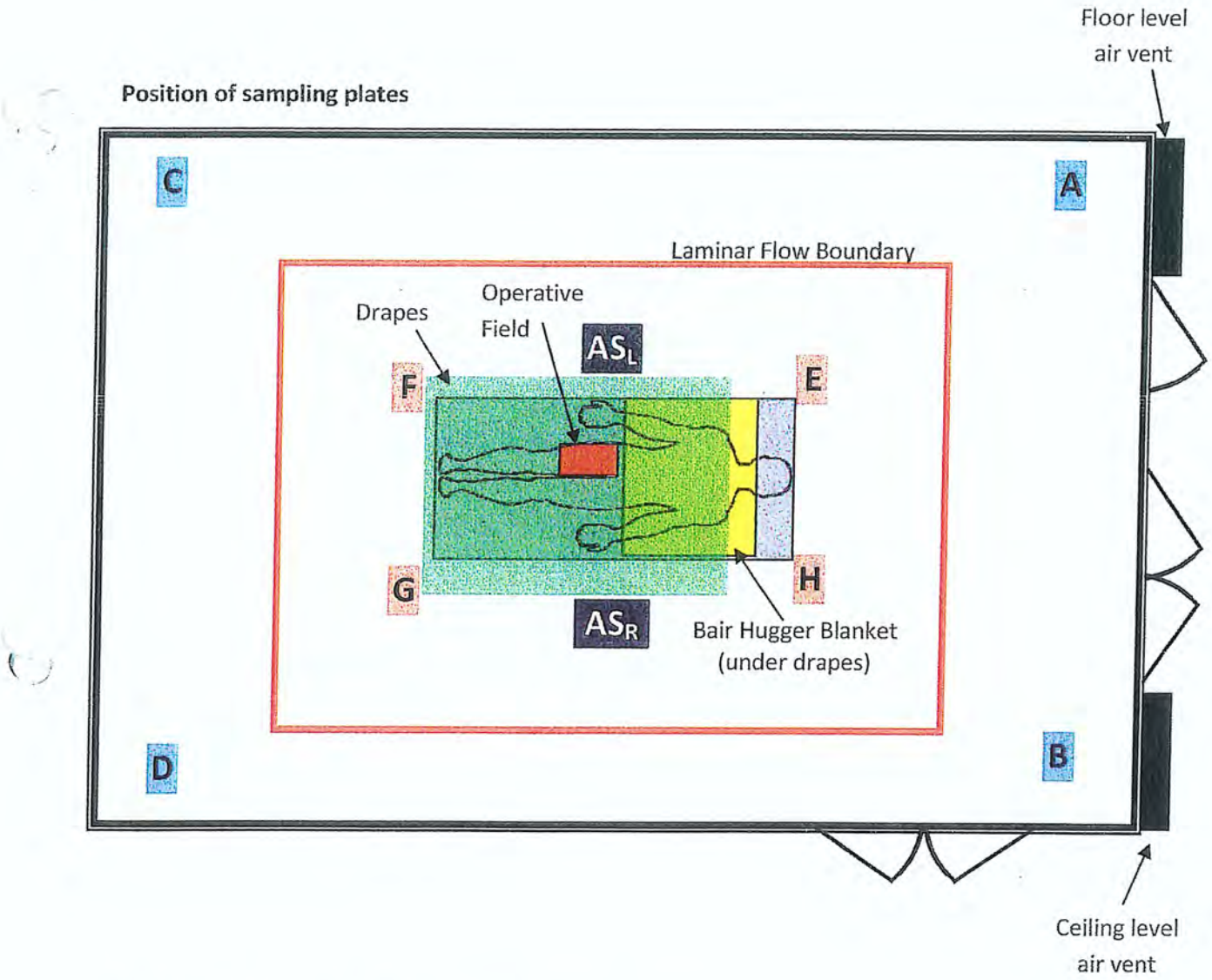
'Background,' or 'Long term' plates remained out for the duration of all 4 experiments, and were positioned at the corners of the operating theatre. Long term plates were labelled A, B, C and D. Shorter term plates were refreshed for each experiment, and were positioned near the corners of the operating table. Short term plates were labelled E, F G and H.

In addition, discrete samples of air were taken for bacterial sampling during experiments. A Sarstedt® air sampler was used, placed on a trolley at the height of the operative field. Samples were collected for 5 minutes, drawing 500 litres of air over a CBA culture plate. The sampler was moved between positions AS_L and AS_R as shown on the diagram in between sampling periods, with a fresh plate being used for each discrete sample.

The Handilaz particle counter was programmed to count continuously during each experiment, outputting results at 1 minute intervals. Using aseptic technique, the machine was covered with a sterile drape (save for the air inlet port) immediately after the patient had been draped. The particle counter was set up as shown in the photograph, with the inlet 1cm from the operative field surface (See Fig xx). The bacterial sampler on its trolley (resting on a sterile drape) was moved into position only when sampling was ongoing and was removed when it was inactive. After the experiment was set up, 10 minutes were allowed to elapse for the system to equilibrate.

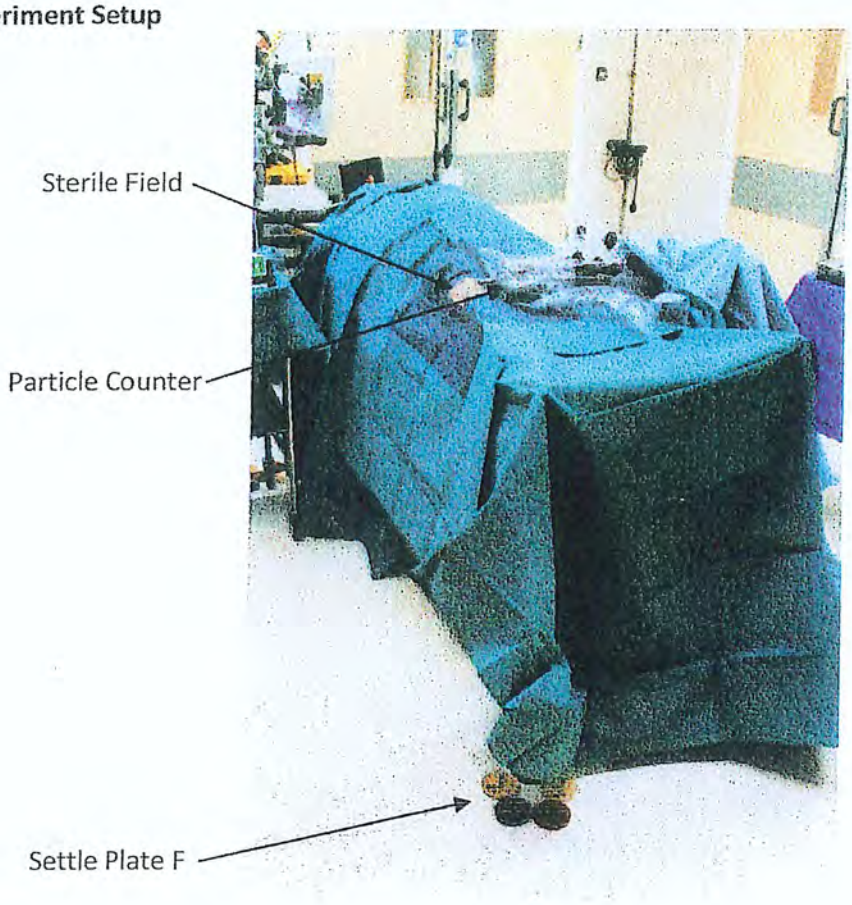
Simulated operation: Each experiment used one of the authors as a volunteer patient. The patient wore a surgical face mask and theatre cap and was positioned supine on an operating table in the middle of the laminar flow zone. Table height was set at xxx cm ***(same as height of standard trolley – Paul to measure)***. A forced air warming blanket attached to the manufacturer-recommended warming device (Bair Hugger Model 505@ - Arizant UK) was placed over the patient's torso and arms. Two of the authors simulating the surgeons used a standard surgical scrub technique with 2% chlorhexidine for 5 minutes and wore caps, masks, sterile surgical gowns and gloves.

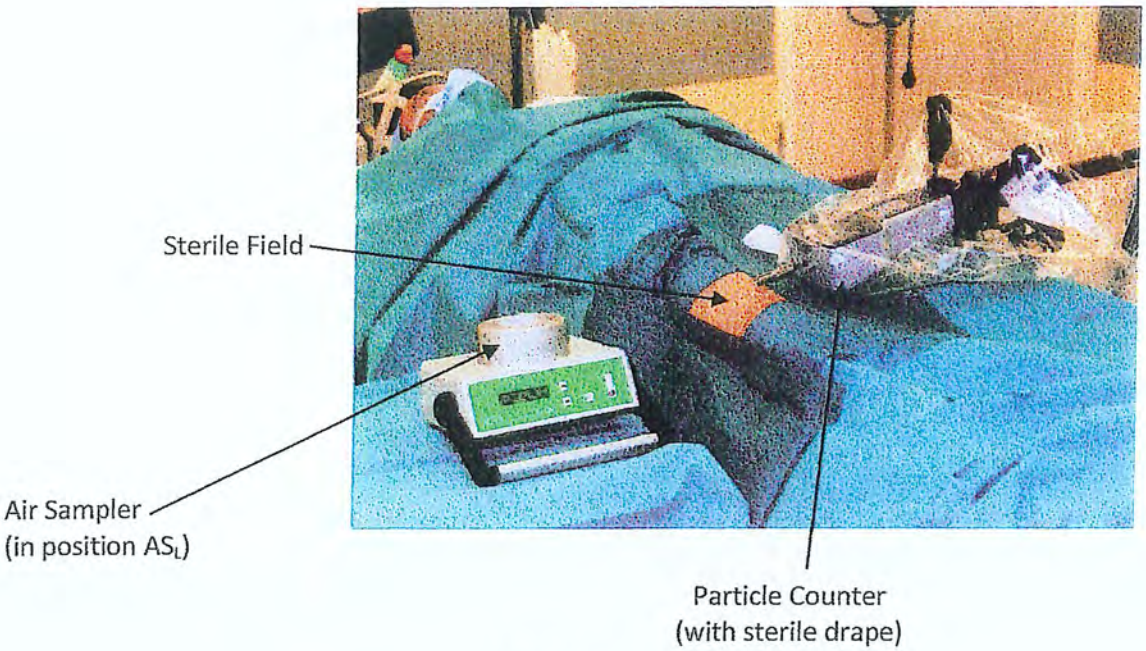
The surgical site measuring 10 x 10 cm was pre-marked on the anterior surface of the volunteer patient and this area was aseptically cleansed using 2% chlorhexidine and allowed to dry. The surgical site was isolated with sterile adhesive disposable surgical drapes. The drapes covered the patient, Bair Hugger@ blanket and the operating table. Added care was taken to ensure an airtight seal between skin and drape, to avoid airflow from the Bair Hugger blanket directly passing over the operative field. The bottom of the surgical drapes was no more than 20cm from the floor.



Settle plates were Labelled A-G
Bacterial air sampling at positions ASL (left) and ASR (right)

Experiment Setup





The particle counter was set up as shown, with the inlet 1cm from the operative field surface. The bacterial sampler on its trolley (resting on a sterile drape) was moved into position only when sampling was ongoing and was removed when it was inactive.

All phases of each experiment were timed at 10 minutes, with no gap between phases. After setup had been completed, movement in theatre was stopped to allow the system to equilibrate. The phases were as follows:

Equilibration Phase: 10 minutes, no movement in theatre, Bair Hugger Switched off

Phase 1: 10 minutes, no movement in theatre, Bair Hugger Switched off.
Phase 2: 10 minutes, no movement in theatre, Bair Hugger Switched on
Phase 3: 10 minutes, scrubbed and gowned surgeon moved next to operative field as if to operate.

Sampling protocols

Background Bacterial Settle Samples:
Bacterial settle plates A-D, remained in position at 4 corners of theatre while all experiments were carried out

Table Bacterial Settle samples:
Bacterial Settle Plates E-H; placed at 4 corners of operating table before each experiment was set up. Taken up an hour later before apparatus was deconstructed.

Airborne Particle Sampling
Airborne particle sampling was continuous throughout all phases, including the settle phase. The instrument was set to output particle counts at 1 minute intervals.

Airborne Bacterial Sampling
The Sarstedt® air sampler was used to take samples at several points during each experiment, from positions AS_L and AS_R

Pre-prep – Sampling from AS_L and AS_R sequentially, before the patient entered theatre

During Preparation – Sampling from AS_L only while patient was being prepped and draped

No bacterial air samples were taken during the settle phase.

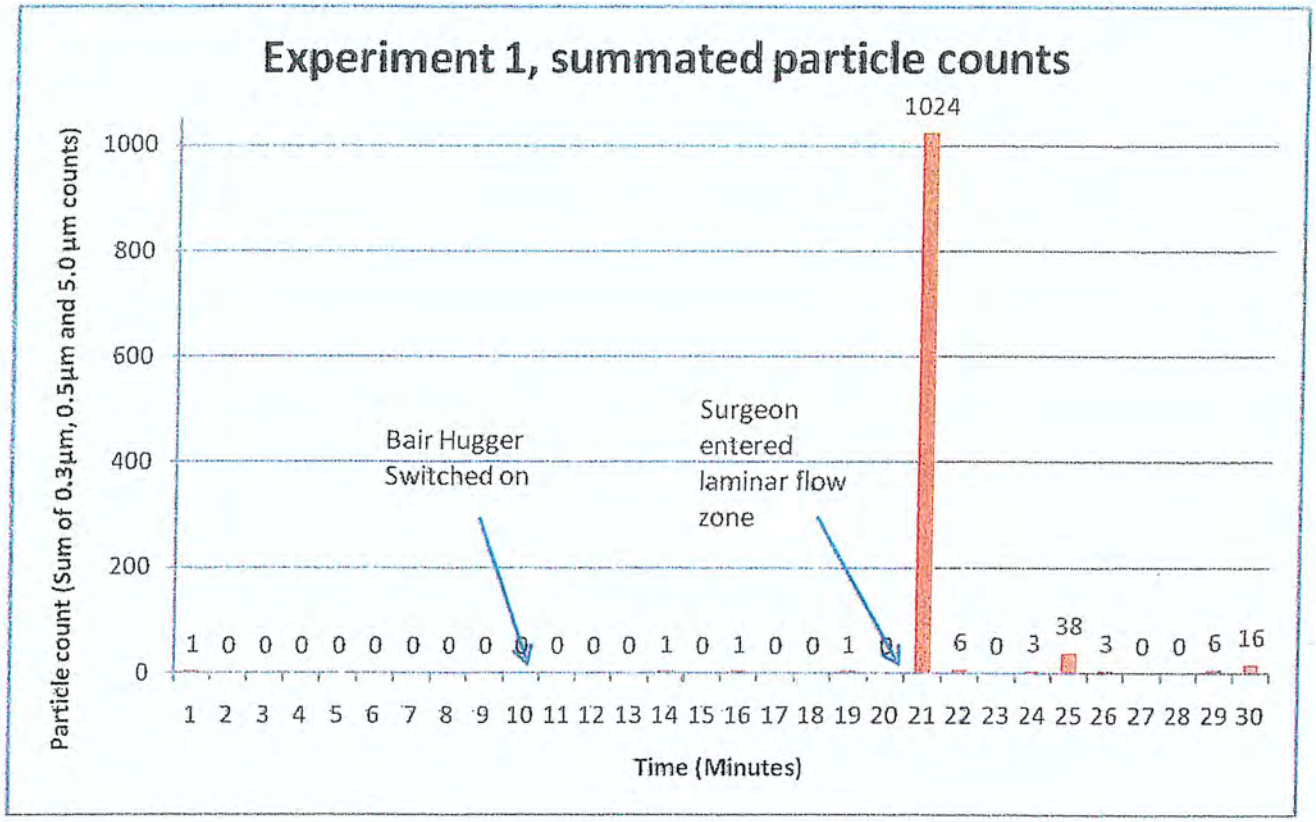
Phase I – Sampled from AS_L only after simulated operation had started.
Phase II – Sampled from AS_L only after Bair Hugger was switched on.
Phase III – Sampled from AS_L and AS_R while surgeon in position and Bair Hugger switched on.

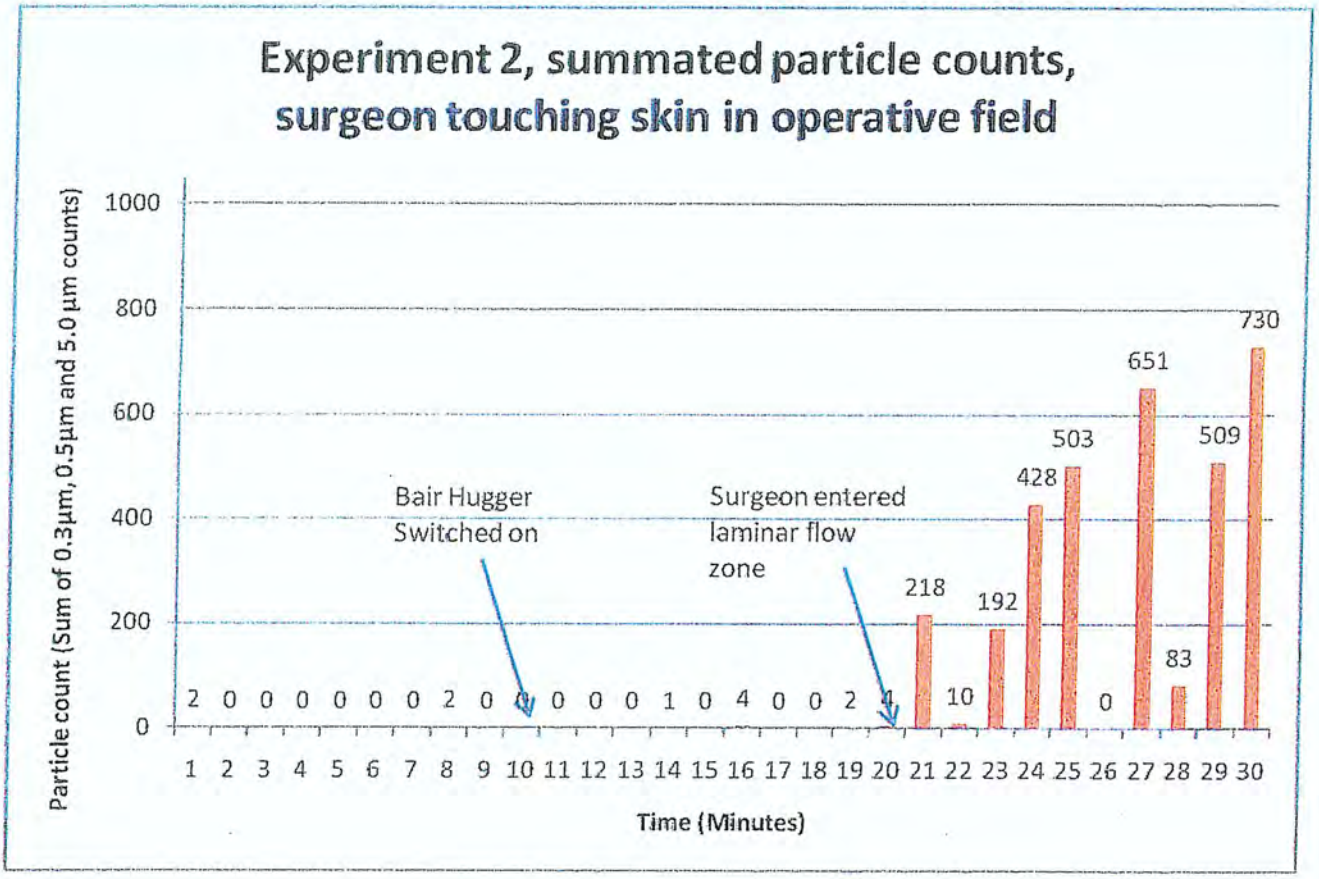
This method was repeated for the 4 experiments. A variation in experiment 4 was that the surgeon continually touched the skin of the operative field with their gloved hand.

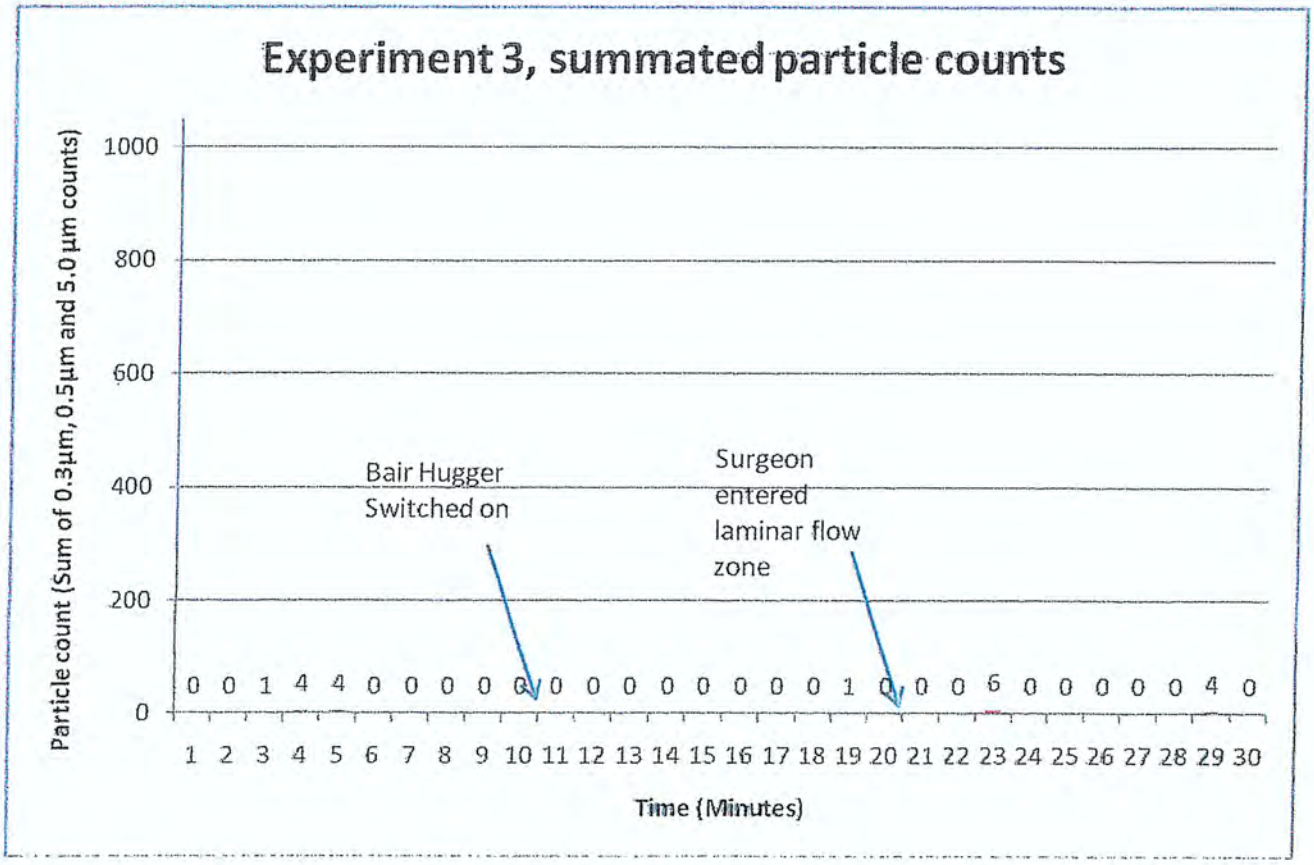
Results

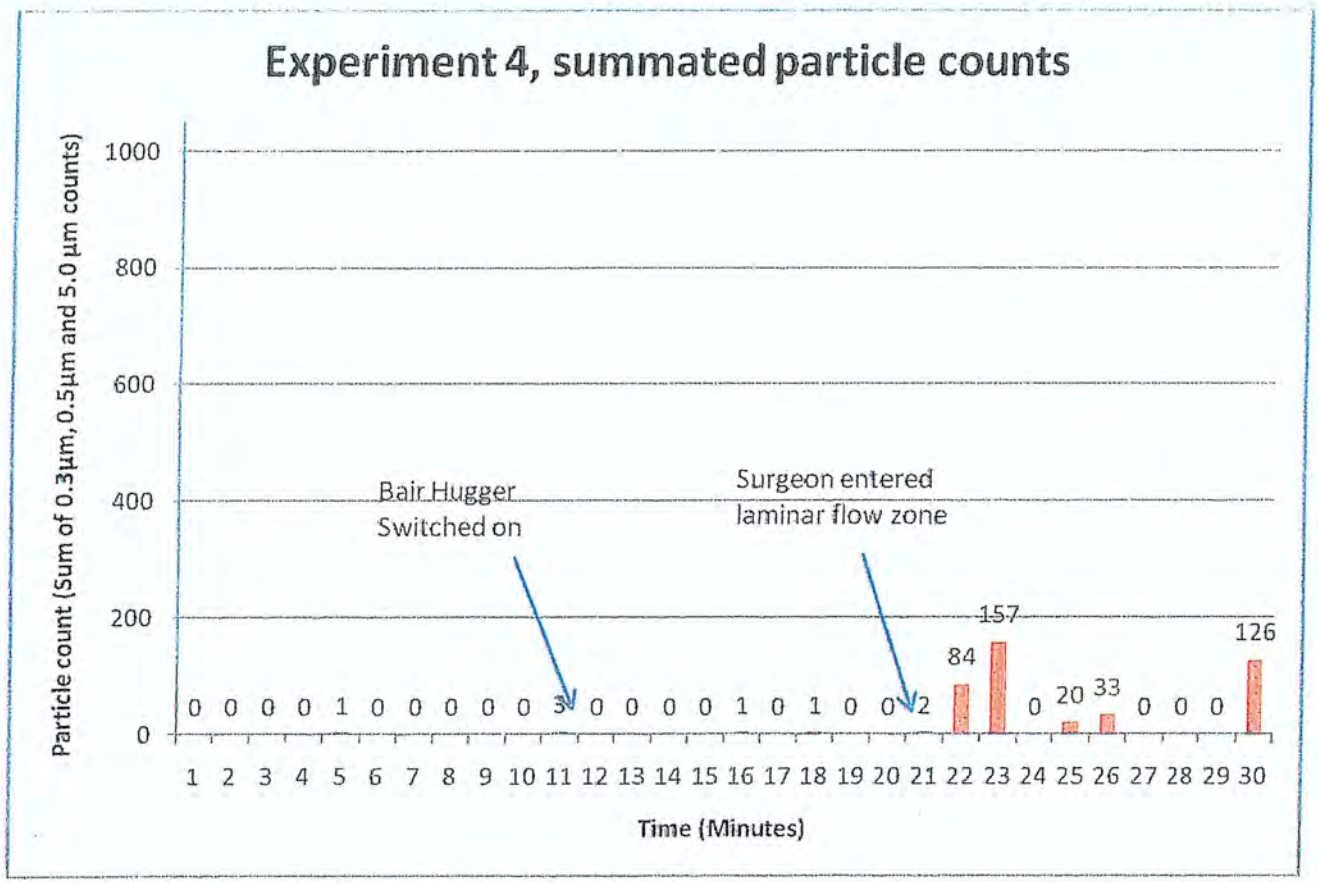
Results – Particle counts

The figures shown represent the sum of particles counted at 0.3µm, 0.5µm and 5.0µm in size.




Experiment 2, summated particle counts,
surgeon touching skin in operative field
Particle count (Sum of 0.3µm, 0.5µm and 5.0 µm counts)
1000
800
600
400
200
0
Bair Hugger
Switched on
Surgeon entered
laminar flow
zone
2 0 0 0 0 0 0 2 0 0 0 0 0 0 1 0 4 0 0 2 4 218 10 192 428 503 0 651 83 509 730
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
Time (Minutes)


Experiment 3, summated particle counts
Particle count (Sum of 0.3µm, 0.5µm and 5.0 µm counts)
1000
800
600
400
200
0
Bair Hugger
Switched on
Surgeon
entered
laminar flow
zone
0 0 1 4 4 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 6 0 0 0 0 0 4 0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
Time (Minutes)



Results – settle plates

Table 1 shows that there was minimal numbers of bacteria isolated from settle plates opened for 4 hrs. The settle plates from position C showed the highest numbers of bacteria. There were no fungi isolated.

Table 1 Counts of microorganisms from settle plates within the operating theatre.

Position	CBA	MRSA	CLED	C. diff	SAB
A	7cfu	1 cfu	8 cfu	0	0
B	1cfu	0	0	0	0
C	28cfu	2 cfu	13 cfu	0	0
D	10cfu	0	7 cfu	0	0

Table 2 shows that there was minimal numbers of bacteria isolated from settle plates opened for 4 hrs. The settle plates from position C showed the highest numbers of bacteria. There were no fungi isolated

Table 2 Counts of microorganisms from settle plates within the laminar flow hood at positions surrounding the theatre table

Position	CBA	MRSA	CLED	SAB	C. diff
E Pre-sample	0	0	0	0	0

	Experiment 1	0	0	0	0	0
	Experiment 2	0	0	0	0	0
	Experiment 3	0	0	0	0	0
	Experiment 4	2cfu	0	1cfu	0	0
F	Pre-sample	0	0	0	0	0
	Experiment 1	0	0	0	0	0
	Experiment 2	0	0	0	0	0
	Experiment 3	0	0	0	0	0
	Experiment 4	2cfu	0	0	0	0
G	Pre-sample	0	0	1cfu	0	0
	Experiment 1	1cfu	0	5cfu	0	0
	Experiment 2	0	0	0	0	0
	Experiment 3	5cfu	0	1cfu	0	0
	Experiment 4	1cfu	0	1cfu	0	0
H	Pre-sample	0	0	4cfu	0	0
	Experiment 1	1cfu	0	4cfu	0	0
	Experiment 2	4cfu	0	1cfu	0	0
	Experiment 3	0	0	1cfu	0	0
	Experiment 4	7cfu	0	0	0	0

The bacteria isolated from the settle plates consisted of coagulase negative staphylococci, diphtheroids and micrococci (skin organisms). **No** coliforms, MRSA, *Staphylococcus aureus* , *Clostridium difficile*, or *candida albicans* were isolated.

Air Sampling for Bacteria - Results

The results of air sampling during the operating procedures are shown below.

Phase	Position of Sampling	Experiment 1 (CFU count)	Experiment 2 (CFU count)	Experiment 3 (CFU count)	Experiment 4 (CFU count)
Pre-prep (before patient entered theatre	Table Left (AS_L1)	**0**	**0**	**1**	**0**
	Table Right (AS_R1)	**0**	**0**	**0**	**0**
During patient Preparation	Table Left (AS_L2)	**1**	**0**	**0**	**0**
Experiment running, Bair hugger turned off	Table Left (AS_L3)	**0**	**1**	**0**	**0**
Experiment running, Bair Hugger Turned on	Table Left (AS_L4)	**0**	**0**	**0**	**0**
Experiment Running, Bair	Table Left (AS_L5)	**0**	**0**	**0**	**0**

Hugger on and Surgeon next to field	Table Right (AS_R5)	1	4	2	1

The bacteria isolated from the air samples were coagulase negative staphylococci and micrococci (skin organisms). **No** coliforms, MRSA, *Staphylococcus aureus* , *Clostridium difficile*, or *candida albicans* were isolated.

The patient's operative field was swabbed for bacteria before and after preparation and draping. No significant contamination was discovered.

The outlet pipe of the Bair Hugger unit was swabbed after the experiments. No significant contamination was found. The warming device was switched on and vented directly onto a CBA culture plate. No microorganisms were grown.

DISCUSSION

Operative field isolation and aseptic skin preparation was performed to the standards used in many orthopaedic procedures ensuring a good seal between skin and adhesive drapes at the margins of the field.
The particle counts measured from the four experiments show that when the surgeon enters the vicinity of the operative field, particle count rise in that zone. This is most marked when the surgeon touches the disinfected skin. This could represent epithelial particle shedding from the patient.
However, there is no suggestion from these results that turning on the Bair Hugger makes any difference to operative field particle counts. Settle plates, airborne particle content sampling of operating theatre. Bacterial sampling from operative field and force air warming device have shown that there were very low numbers of skin bacteria found within these various areas of the operating theatre.
These experiments show no notable increase in either ambient particle count or bacterial count in the vicinity of an operative field when a forced air warming device is being used. Low bacterial counts in all experiments are reassuring – however the potential for introduction of airborne particles from outside the laminar flow zone to the operative field is of potential concern; these could be pathogens themselves, or sterile particles that form a nidus for pathogen growth. [5]
Further studies are required to ascertain if there is any relationship between the increase in particle levels seen here and a possible increase in pathogens during operative procedures.

Conclusions
There is no evidence from these data that the Bair Hugger intraoperative warming device increases bacterial contamination of an operative field in a laminar flow theatre, intraoperatively.

NOTES – haven't re-done the references yet, will do so

Results, I haven't yet swapped round experiment 2 and 4.

EXHIBIT DX17

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

- - - - - - - - - - - - - - - - - - - -

IN THE MATTER OF	)
	)
IN RE BAIR HUGGER FORCED AIR WARMING PRODUCTS LIABILITY LITIGATION	)
	)
Plaintiff,	)
	)PRETRIAL ORDER NO: 7
v.	)Protective Order
	)MDL No. 15-2666
3M COMPANY AND ARIZANT HEALTHCARE INC.	)(JNE/FLN)
	)
Defendant.	)

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DEPOSITION OF PAUL MCGOVERN

VOLUME I

Wednesday, January 4, 2017

AT: FAEGER BAKER DANIELS

Taken at:

7 Pilgrim Street
London EC4V 6LB
United Kingdom

Court Reporter: Louise Pepper

Videographer: Simon Addinsell

Job No: 117119

DR. PAUL MCGOVERN

don't know if the hospital or the trust made a whole scale or a wholesale switch to a different device or different technology. I don't know.

Q. And when you left there, was Bair Hugger still being used for arthroplasties?

(Reporter clarification.)

A. I don't remember.

Q. Okay. So, let's go back to 2009 when you started at Wansbeck. Was that the first time you would have had any contact with Mr. Mike Reed?

A. Yes. Err ... no. Any contact whatsoever would probably have been in 2008 because he is -- or was -- fairly senior in the training of -- involved in the training of orthopedic surgeons in the northern deanery. So it is likely I would have received e-mails from him prior to 2009, probably in 2008. They would have been not to me personally; they would have been group e-mails. I don't remember the content of them, but it is likely I would have had received communication from him before then, but the first time that I started working with him was in 2009.

(Reporter clarification.)

Q. What month in 2009 did you start at Wansbeck?

A. August.

Q. Using that as kind of a benchmark time frame, when

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you started at Wansbeck in August 2009, had you had any involvement in any activity or attending any seminar, reading any material, anything that would have raised any questions about the use of forced-air warming of Bair Hugger in orthopedic surgery?

A. I don't remember.

Q. Now, certainly subsequent to the time you started at Wansbeck, something got you involved in, and interested in, forced-air warming?

A. Yes.

Q. What was -- do you recall what it was that first attracted your interest?

A. As a training surgeon, there is -- one is encouraged to undertake audit activity and research activity. And so it's common practice for a surgical doctor to speak to their boss, their consultant, or someone senior to them, to ask if any research is ongoing in the department. And one of Mike Reed's research interests is infection in the operative or the perioperative period. And in fact, it's something that is taken very seriously in all hospitals, in all orthopedic departments, but Wansbeck -- there was a culture in the department of being very vigilant for possible sources of infection to -- with a view to reducing overall infection rate.

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And so I was introduced to the research in question by Mike Reed, following an approach from myself to get involved with some research that was ongoing in the department.

Q. When you started in August of 2009 at Wansbeck, were you aware of any concerns that the NHS had expressed about the rate of infections in the orthopedics department at the -- in the Northumbria Trust hospitals?

A. I was not there that the NHS had expressed any concerns.

Q. And as you sit here today, you never heard that there had been concerns expressed about how high the rates of infection had been?

A. So, you say the NHS. What I took to mean by that was the higher body of the NHS. I wasn't aware if they had particularly expressed concerns. However, I was aware that there were concerns within the department that the infection rate at that trust was higher than would have been considered ideal, and there were efforts to bring it down.

Q. And when you started, were -- had all those efforts to bring it down already been undertaken, or were there still some efforts that were ongoing or yet to be implemented?

MR. SACCHET: Object to form.

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(Reporter clarification.)

MR. C. GORDON: That's actually a good objection. I'll rephrase the question.

BY MR. C. GORDON:

Q. When you started in August 2009, are you aware of steps that had already been taken prior to August 2009 to reduce the infection rates at those hospitals, the Northampton Trust hospitals?

A. I was not aware of steps at the time.

Q. Okay. Subsequent to your starting there in August 2009, were you aware of any steps that were taken or procedures that were implemented, practices that were implemented, to attempt to reduce the infection rate?

A. There's a constant and ongoing effort, in any responsibly-run surgical department, to reduce infection rates, particularly in orthopedics. And so it's not a question, to my recollection, that there was a period where there weren't steps to reduce infection rates, and subsequent change. There are always efforts to reduce infection in orthopedics departments. So I don't remember a specific time when practice was -- where one could draw a line in the sand. I don't remember a specific time when that was. My recollection is of a department that was always trying to reduce infection rates.

Q. We'll come back to that soon, in some detail, later. So, when you started in August 2009, Mike Reed was your supervisor?

A. Yes.

Q. And you asked him what kind of research he was doing that you might become involved in; is that fair?

A. Yes.

Q. And what was the first thing that he involved you in?

A. The first thing I remember is -- was a discussion about infection rates and a project to investigate the possibility of infection, or the possibility of a Bair Hugger influencing bacterial load in an operating room, possibly increasing infection rates.

Q. And what was your understanding of how that research issue had arisen? Because that's -- what was the genesis of it, to your understanding?

A. Sorry, could you repeat the question?

Q. As I understand it, you asked Mr. Reed: "What research can I get involved in?"

And he said: "We're looking at Bair Hugger and its possible impact on influencing the bacterial load."

Do you know how that it came to be that that was a -- that was something that Mr. Reed was looking at?

A. No, I don't know how that specifically came to be.

Q. At any time, had you -- strike that.

When you talk about the bacterial load, could you explain what you mean?

A. Yes. So, an operating room is a clean environment and one in which the presence of any possible source of infection to the patient must be reduced so far as is possible. And when I say bacterial load in this specific case, what I refer to are particles in the air which may have bacteria on them. Generally, these include dust particles from the patient, from circulating theater staff and the scrubs team, skin cells, water droplets or moisture droplets from exhaled air from the surgical team, from the patient, from the process of surgery. All particles which may be in the air which may themselves carry bacteria which have the potential to settle in an operative wound and the potential to cause infection.

Q. Is it the bacteria that actually causes the infection, or the particles?

A. The bacteria causes the infection. The particles are the vector for the infection, and so the bacteria will stick to particles. They are all around us right now. The air is loaded with particles anywhere you are, unless you have a device or an environment which is specifically

controlled to reduce the count of airborne particles.

Q. Do all particles carry bacteria?

A. No.

Q. Is there some generally accepted rule of thumb as to what percentage of particles carry bacteria?

A. Not that I'm aware of, because it depends on the situation. It depends on the environment.

Q. So, in an operating room, if there are particles present, they may or may not carry bacteria?

A. Correct.

Q. And if particles that don't carry bacteria settle on the surgical wound, do they increase the risk of infection?

A. If particles that don't carry bacteria settle on the surgical wound, do they increase the chance of infection? Potentially, yes, but that's not something which -- potentially, yes.

Q. How would a bacteria-free particle potentially increase the risk of infection?

A. It could cause irritation. If a particle were toxic, if it were -- if it caused a reaction in the patient, to the patient's immune system, then that could cause inflammation and -- which could contribute to infection, because excess of inflammation can reduce the body's ability

to fight infection. So in itself it would not cause infection, but it could create or assist the creation of a condition which could increase predisposition to infection. However, it's very unlikely.

Q. So when you speak of bacterial load in connection with this initial research activity that you became involved in, was the focus on transmission of actual bacteria that would -- that could be settled, or that could settle on the operative site?

A. So ... just repeat the question, please?

Q. It was a very poorly phrased question. I'll rephrase it.

In your initial research activities at Wansbeck under Mr. Reed where you looking at bacterial load and the impact of the Bair Hugger, is it correct to say that the bacterial load you're talking about is actual bacteria that could potentially be transmitted to the operative site?

A. Initially, we looked at -- we attempted to measure bacteria directly, as well as indirectly. So we've used particles, airborne particles, as a model or as -- almost as a way of measuring potential for infection. Initially we did an experiment which attempted to pick up or detect bacteria -- excuse me -- as well as attempting to detect

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A. It is indeed, yes, another draft of this study that we've been talking about.

Q. And does the fact that this one has a list of names -- author names on it, suggest where it comes in the sequence of drafts?

A. It is likely to be after the first document we've discussed, but I do not know if this is before or after the second document that we've discussed. I can't tell.

Q. If you turn to page 3626, there are a couple of notes highlighted in yellow. One notes:

"Haven't re-done the references yet, will do so.

"Results, I haven't swapped round experiment 2 and 4."

A. Yes.

Q. Are those your notes?

A. I don't remember.

Q. You described a process whereby this the write-up of this experiment went through several versions with input from several different people; is that right?

A. Yes.

Q. Do you know who had input in addition to the people listed on 3615?

A. I am not aware that anyone else had any -- I don't recall anyone else having any input into the write-up.

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THE VIDEOGRAPHER: Can I pause you a second. Your mic has fallen off.

BY MR. C. GORDON:

Q. Was this paper ever finalized?

A. Define "finalized".

Q. Where everybody who was involved in its authorship said, "Yep, this is a final version. I'm good with this."

A. No, I don't think so. A finalized paper would be one which had been accepted and published in a peer-reviewed journal.

Q. Okay. Was this ever submitted to any journal for publication?

A. This experiment was submitted to a meeting as a presentation. I can't remember which meeting, but it was rejected -- I think it was the American Academy of Orthopedic Surgeons. I would have to check that, but that was the meeting it was submitted to. So it was submitted and rejected.

Q. And when you say it was submitted, you're talking about a one-page summary?

A. An abstract of this. The form for such presentations is that an abstract is submitted and the study is accepted or rejected, based on that abstract.

Q. Was it submitted to more than one? Was the

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abstract submitted to more than one group?

A. Not to my recollection.

Q. Was there any discussion about submitting the full paper, with the complete results and the analysis and the discussion, to a journal for publication?

A. Well, the process of writing up is with the intention of submitting it to a journal. But I think most clinicians would agree that the barrier of entry, or the -- we would agree that it is harder to get something published in a journal than it is to have something presented at a meeting. And so all these documents that we've been discussing were working towards the intention of having it published in a journal. But having been peer reviewed by the review process, the abstract being reviewed and rejected, at that point it wasn't taken further.

Q. Who made the decision not to pursue this any further by trying to submit it to a publication, or submit the abstract to other organizations?

A. I don't remember.

Q. At what point did you first meet Mark Albrecht?

A. I don't remember.

Q. Do you recall the circumstances under which you first met him?

A. It would have been in the U.K. and it's likely that

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it was -- well, in the Newcastle area. It would have been in relation to a subsequent experiment looking at airflows in operating rooms, operating theaters.

Q. Was Professor Edwards-Jones involved in any discussions about whether to try to submit this to any publication?

A. I don't remember if professor Edwards-Jones was involved in discussions about submission, or which publications or meetings would be targeted for submission. I remember the discussions with Professor Edwards-Jones were regarding the microbiology and plates, things of that regard, but I don't remember if discussions with Professor Edwards-Jones involved a submission.

Q. I want to be sure I understand. Your testimony is that because one conference group rejected a one-page summary for a presentation to that conference, you decided: that's it. We're not going to do anything further with this research?

MR. SACCHET: Object to form.

A. I think that is part of the reason that this wasn't pursued further. I think that in this case the experiment is poorly designed, and because the -- because presenting something in a meeting is generally easier than getting something published, it seemed extremely unlikely, so as to

a huge and very complex study, and one which, without a very, very large amount of funding, would be unfeasible.

Q. Do you recall any discussions with anyone about trying to accomplish a study along the lines you've just described?

A. I've had frequent discussions with Mike Reed, but not in terms of actually trying to plan a study, but in terms of mentioning that that would be desirable. That would -- a well designed, multicenter, randomized control study would provide more robust information which would be valuable.

Q. So at what point after you had done this study did you decide to do further research on the Bair Hugger?

A. In terms of time, I don't remember. It was sometime after the experiment was conducted. This, as you can see, went through multiple revisions. So I spent some effort trying to get this up to standard. But the process of a junior doctor writing their first paper is a torturous one, and a long one, as can be seen by the many slightly varying revisions that I've produced. I don't remember when the next study started. I don't remember if writing up of this continued after, during or before the subsequent investigations took place.

I had the particle counter and I was continuing to try to learn how to use it. I would informally sample air in operating rooms at home to see what type of scenarios produced what type of results with it, to try and learn how to use it better. But I don't remember the exact timescales of those.

Q. What was the next Bair Hugger related research activity you undertook?

A. I think it was the study in which we used the -- well, the next experiment that I was involved in. So I was involved in writing up several papers and involved in the writing phase of those, but the next experiment that I was involved in was, to the best of my recollection, one in which we used a bubble generator to visualize airflow in the presenting room, in an experimental set-up.

Q. Whose idea was that?

A. Whose idea was?

Q. To use a bubble generator to visualize airflow?

A. I don't remember.

Q. Was it yours?

A. It was not mine.

Q. Was it somebody connected with Augustine?

A. I don't --

MR. SACCHET: Objection to form.

BY MR. C. GORDON:

Q. Was Mark Albrecht involved in this bubble visualization?

A. Yes.

Q. How was he involved?

A. Mark Albrecht was involved, was in the UK for the experiment, for collection of some of the data, and helped to design the experiment, helped conduct the data collection, helped -- well, he was the person who knew how to use the bubble generator. And so he used that, directed its use, and was involved in statistical analysis and writing up.

Q. What was your role in that?

A. My role was to help design the theater layout, the operating room layout, and to advise on patient positioning, on surgeon positioning, anesthesia screen positioning, anesthesiologist positioning, and to advise on how an operation was set-up in real life, in an effort to best simulate a situation which was as realistic as possible.

Q. Do you know Robin Humble?

A. I do.

Q. When did you first meet him?

A. I don't remember. I don't remember if it was before this bacterial particle sampling experiment we've

been discussing. I don't remember if it was before that or after that.

Q. In what context did you meet him?

A. I don't remember when I met him. I don't remember the context I met Robin Humble in.

Q. Whenever you first met him, what was your understanding of who he was?

A. My understanding now is that he is -- he works with HotDog, the company HotDog, to distribute it in the U.K. I don't remember what my understanding of his role was at that time.

Q. Did you meet him in a professional context or a social context?

A. I remember working -- I remember him being present during the experiments with the -- or some of the experiments at Wansbeck Hospital using the bubble generator. I don't remember if I have met him before in another context.

Q. Did he have anything to do with the actual running of the experiment, the microbiology one that we've been --

A. Not to my recollection.

Q. Did you meet him before or after you met Albrecht?

A. I don't remember. It may have been around the same time, but I don't remember if I met him before or after Mark

Albrecht. I don't remember who was at Wansbeck Hospital first. I don't remember if I met one of them and another one came on a different day. I don't remember if it was in the same day, a couple of days, weekends. I don't remember meeting Robin Humble. I remember him being at Wansbeck Hospital.

Q. In the first bubble experiment you did, you actually compared Bair Hugger to HotDog, right?

A. I believe so, yes.

Q. Had Wansbeck Hospital acquired a HotDog unit prior to that?

A. I don't remember. I remember that Wansbeck Hospital did look at and eventually transfer over to HotDog as their warming solution of choice. I don't remember if that process had occurred, or if it had started at the time of the bubble experiment. I think it had not happened. I don't think Wansbeck was running HotDogs as part of their general practice at the time of that experiment, but I can't remember the exact dates.

Q. Do you know how it came to be that Wansbeck had a HotDog unit to even use when you did that bubble -- that first bubble experiment?

A. I don't.

Q. Did you have any input into the initial decision to

do the bubble experiment?

A. I was working on the -- this project, and it seemed -- as I'd been working with Mike Reed in the area, I was a junior doctor under him, and I worked -- he asked me if I wanted to be involved in more research in it. I haven't -- my aim was to get a paper published. That's the -- that was the prime reason to get involved in the very first place, was because I wanted to get a paper, or more than one paper, published, which is why I went through so many iterations of this, because I did want to publish something. I was offered to be involved with more studies, and so I agreed.

Q. Going back to the microbiology study, given your eagerness to publish a paper and all the effort you put into the various versions of it, why didn't you just try submitting it somewhere?

A. A couple of reasons. First, it seemed futile. Second, I haven't finished every piece of audit or research work that I've started. I've got quite a lot of things which fall by the wayside. It's not uncommon for me, and I think many of my colleagues, to start something and realize that you're barking up the wrong tree or going down a dead end. And so this is one of several efforts. I've had other audits and other -- no research in this field, but

in other areas which I've started, and then realized that it wasn't going to achieve anything, and then not continued with it.

Q. Had you published anything prior to the time you did the microbiology study?

A. I had been a very junior author on one paper which looked at the development of electronic software in a trauma unit. That was in 2007, and my involvement in that was performing an audit on, I think, surgeons' perceptions of how trauma meetings are performed in the morning meeting in a surgical unit that I worked in in UCLH, when I was a second-year doctor. And so this is the first experiment which I was more closely involved with in the design of. I had not done any research or anything in this area, and tried to design anything before. I had one publication but was a very junior author and did a very small part of the larger projects.

Q. Did there come a point in time with the microbiology study, when you'd gone through various drafts and put all this effort in, that somebody put their hand on your shoulder and said, "Mark, give this one up. Move on to something else."

A. Mark?

Q. I'm sorry. "Paul".

A. No. At no point did anyone say "This is a" -- you know, "Give this up." I -- as a more senior trainee, Ms. Srinivas was not involved initially, but helped me quite a lot with trying to get this up to a standard which we thought might be publishable. But really, this was not a situation of anyone discouraging me; this was a situation of me realizing that it wasn't going to get published, particularly after it had been rejected for a scientific meeting. And going through all the iterations, seeing that there was very little substance which a reviewer would grab on to and think: this is worth publishing.

And I think that -- I still have that opinion. Having been involved with the review process more, as I've got more senior, if this were presented to me as a reviewer, I'd reject it. It doesn't -- it's -- I'd try and, if I were reviewing it, offer some helpful advice and say that "You need to be a bit more focused as to what you're trying to show and have an idea of how you're going to show it," but in this form, and any forms that we got to, it is not something that would be in a peer-reviewed journal that would be of sufficient note to be worth my career.

You can get something published in some journals, but if they're not listed on PubMed, if